Queen Mary University of London

And

Barts Health NHS Trust

RESEARCH MANAGEMENT POLICIES

Approved by Queen Mary University of London Senate, 9 March 2016*

Approved by Barts Health NHS Trust Policy Committee, 24 March 2016*

* unless otherwise stated.

CONTENTS

Introduction

These core policies have been constructed to enable Barts Health NHS Trust (BH)) and Queen Mary University of London (QMUL), to develop coherent and collaborative approaches to managing their research activities and the Joint Research Management Office (JRMO). They are designed to ensure there is a clear policy framework to address regulatory and legal requirements for research managers and research active staff.

QMUL and BH are partners in research involving human subjects and are supported in this through a single set of policies, systems and processes via the JRMO. The Research Governance Framework and all other related regulations and laws require all research active organisations to have systems in place to meet their requirements. Establishing a common set of principles provides a sound basis for collaboration in research across the NHS and academic boundary, ensuring that the researchers who are often active in both organisations can work to a clear and largely consistent set of standards and policies.

These Policies have existed since 2003 and have been constructed to meet the requirements of the National Institute for Health Research, Research Support Services Framework and have been reviewed and revised as and when needed. The Policies are either individual organisational policies (where a joint policy is not appropriate or feasible) or were drafted by a working group drawn from managers in the Joint Research Management Office (JRMO) and Professional Services Managers in QMUL and BH.

Regulatory guidelines are regularly updated so these policies will be reviewed every two years to ensure they remain consistent with legal and regulatory requirements.

These policies should be read in conjunction with associated related institutional policies including HR, Financial Regulations and other policies relating to the governance of both QMUL and BH.

Section A: Standards for Research

1. Ethics

1.1 Background

Robust scrutiny of the ethical aspects of any research that involves human subjects is at the heart of the Research Governance Framework. It is the responsibility of all researchers to ensure that research including research involving animals is conducted to the highest ethical standards, in line with current guidance and UK legislation[1].

1.2 Research involving human subjects

All national and local permissions and approvals must be in place prior to any study activity taking place. Researchers should follow national, local and sponsor guidelines and SOPs to ensure appropriate submissions are made.

Where a researcher is unclear whether their research requires NHS REC or QM ERC and/or local R&D approval, they MUST seek clarification from the JRMO. Contact details can be obtained through the JRMO website.

When research involving human subjects is conducted amongst a team of researchers from different institutions, ethics approval from only one institution, normally the sponsor institution, is sufficient. Copies of ethics committee approvals (or non-approvals) must be copied to JRMO.

Specific definitions exist to define research sites, which have specific implications for ethical approval[2].

All applications for approvals from regulatory bodies such as REC, HRA or MHRA must be submitted using the Integrated Research Application System (IRAS)[3]. Researchers are advised to carry out the IRAS training module prior to completing the form. Advice and guidance should be sought from the JRMO, before completion of the form.

The Investigator has overall responsibility for ensuring that the research meets the standards laid down by the REC. This includes:

- Compliance with requirements to protect the rights, health & safety, privacy and dignity of trial subjects;
- Notification of annual reports to required bodies (e.g. REC, MHRA and sponsor);
- Notification of changes to the protocol to the REC and the JRMO;

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[1] The Royal College of Physicians (1997) Guidelines on the Practice of Ethics Committees in Medical Research Involving Human Subjects.
The Declaration of Helsinki (2000) Ethical Principles for Medical Research involving Human Subjects.
Local Research Ethics Committees HSG (91)5.
Ethics Committee Review of Multicentre Research. Establishment of Multicentre Research Ethics Committees HSG (97)23.
Governance Arrangements for NHS Research Ethics Committees, 2001.
General Medical Council (1999) Good Medical Practice.
Home Office (1986) The Animals (Scientific Procedures) Act
The NC3Rs ARRIVE guidelines to improve the design, analysis and reporting of animal research
The Data Protection Act 1998.
The Research Governance Framework for Health and Social Care 2001 and revised 2005.
The Medicines for Human Use (Clinical Trials) Regulations 2004.
[2] Governance Arrangements for Research Ethics Committees (GAfREC) Harmonised edition, September 2011
[3] Please refer to IRAS user manual located at
https://www.myresearchproject.org.uk/help/Contents/IRASHelp_UserManual.pdf

- Maintaining high standards of record keeping;
- Ensuring participants have given fully informed consent (see Consent Policy);
- Ensuring that research is assessed in accordance with the JRMO Peer Review Policy;
- Ensuring full accountability for all trial supplies (including trial medication, clinical equipment and devices); and
- Ensuring investigator and trial team are appropriately trained in the protocol and the applicable regulations (e.g. GCP and RGF).

For research that falls under the EU directive, investigators and trial team members must attend GCP training prior to study commencement and attend refresher training once every two years thereafter. For research not under the EU directive the investigator and the trial team must attend Research Governance Training prior to commencing research activity and attend refresher training once every two years thereafter.

The JRMO must be kept informed of all proposed and on-going research. For BH or QMUL sponsored studies a copy of the completed ethics application form must be submitted to the JRMO before it is submitted to the REC. The investigator of the study must also keep a copy of the full ethics application form and any correspondence from the REC; this should be filed within the trial master file.

Principal investigators have a duty to ensure that applications for ethical approval are accurate and complete. This includes ensuring that the appropriate documentation has been obtained from regulatory bodies and any commercial or non-commercial sponsor.

Any data that by itself, or in conjunction with other easily obtainable information, can identify a specific person will remain protected by The Data Protection Act 1998. Contracts should draw attention to the obligations of confidentiality and make it clear that the agreement is dependent on the conditions of confidentiality being met.

Investigators must declare on the REC form and to the JRMO any conflicts of interest that may exist between any parties and themselves. Should any commercialisation ensue, as an output of the research, this must be protected as per the existing related joint polices.

Ethical approval should not be viewed as an automatic license to begin research.

Investigators must also ensure they have all the appropriate contractual agreements in place, any additional regulatory approvals and BH or QMUL approval, in particular, a final JRMO approval letter and confirmation of sponsorship is required before a study can commence.

Failure to obtain appropriate ethical approval constitutes research misconduct and may result in formal disciplinary action being taken.

The JRMO will monitor and audit studies to ensure that all research within BH and QMUL has appropriate ethical approval (through an ethics application screening system pre-REC application) and that consent for the research is being taken as specified in the ethics application.

1.3 Research involving animals

QMUL is committed to the highest ethical, humane and welfare standards relating to the use of animals in research. Work in this area is overseen by our Animal Welfare and Ethical Review Body.

We work at all times towards achieving the '3Rs' – Replacement, Reduction and Refinement – with respect to research requiring the use of animals.

QMUL is a signatory to the ARRIVE (Animal Research: Reporting of InVivo Experiments) Guidelines.
We have also recently signed the Concordat on Openness in Animal Research, which means we are committed to being more open about the ways in which animals are used in scientific, medical and veterinary research in the UK.

High standards of humane care and treatment of animals undergoing procedures must be adhered to at all times.

Any member of QMUL staff conducting experiments involving animals has to undergo training, have relevant experience and be authorised by the Home Office via a licensing system.

The Home Office Inspectorate regularly inspects the facilities along with our own appointed veterinary surgeons.

Note: This Policy applies to BH and QMUL as indicated.

2. QMUL policies on research integrity and research ethics

2.1 Research Integrity

Queen Mary is committed to producing and promoting high quality research which is conducted according to the highest standards of integrity. To support these aims, in all fields of research, Queen Mary has adopted the commitments of the UUK "Concordat to support research integrity" which are:

- Maintaining the highest standards of rigour and integrity in all aspects of research;
- Ensuring that research is conducted according to appropriate ethical, legal, and professional frameworks, obligations, and standards;
- Supporting a research environment that is underpinned by a culture of integrity and based on good governance, best practice, and support for the development of researchers;
- Using transparent, robust, and fair processes to deal with allegations of research misconduct should they arise;
- Working together to strengthen the integrity of research and to reviewing progress regularly and openly.

These commitments form an integral part of Queen Mary's approach to the ethical conduct of research, its mission and values. The Queen Mary Strategy and the statement of our values are published at http://www.qmul.ac.uk/strategy/the%20strategy/index.html

All Queen Mary research policies require that ethical risks should be minimised; risks should be appropriately and adequately managed where they cannot be eliminated.
Research must be demonstrably independent.

Conflicts of interest should be avoided; if a conflict cannot be avoided, it should be clearly declared to all those involved in the study, its publication, and any work resulting from it.

The Queen Mary Ethics of Research Committee has been authorised by Senate to advise on all research policies, to oversee their ethical content, and to provide advice on ethical and related issues arising from their implementation. This includes training of researchers, data management, research misconduct, discrimination, confidentiality, and acceptance of funding.

The Senate has granted authority to the Queen Mary Ethics of Research Committee to establish criteria, processes, and procedures to enact this policy and to grant approval to research according to its terms.

2.2. Research with Human Participants

All research involving human participants must have ethical approval. The Ethics of Research Committee is responsible, under authority delegated by Senate, for approving the ethical standards of research involving human participants or materials derived from human participants. All such projects throughout Queen Mary should be submitted to the Committee for approval, except those research studies which fall within the remit of the NHS Research Ethics Committee, or other such recognised bodies.

Research must be conducted with honesty, integrity, and due care for the rights of participants and researchers. Ethical requirements include:

- That participants are treated with care, dignity, and compassion at all times;

- Research should not be intrusive nor otherwise compromise the integrity of the participants or those related to them, or their physical or emotional environment;
- Any incentives offered should not be such as to influence a potential participant to do anything which would be contrary to their best interests;
- Specific permission to make the research enquiries should be obtained and recorded unless it would be unreasonable to do so; that permission should cover the research methodology, the content of the enquiries, and the evidential handling of the research data or findings;
- The research aims, methodology and risks, and the approach to data management, should be clearly and comprehensively explained in writing to each participant at the initial approach, and the participant's written consent must be obtained and should be worded accordingly;
- Anonymity if promised must be safeguarded at all times, as must confidentiality: if the research requires that responses will not be confidential the participant's agreement to this must be specifically and clearly recorded;
- Research data should be managed in compliance with the QMUL Research Data Management Policy;
- Proposed use of the research material must be clearly stated, including possible publication and the form such publication might take; and
- Research with children and young people:
  (i) Research with children and young people under the age of 16, and those who may not be able to give informed consent, should only be carried out with the explicit assent of a parent or guardian and with the consent of the child, unless there are exceptional circumstances which must be approved by the relevant QMUL Ethics of Research Committee;
  (ii) Researchers working with young people aged 16 years and under 18 years should consider the potential risks involved in participating in the research. Research proposals should include an assessment of the environment in which the research is being carried out and any potential risks to participants in order to determine whether assent should be obtained from a parent or carer as well as the consent of the participant. For particularly vulnerable 16–18 year olds (for example if they have a learning disability) and those who may not be able to give informed consent, or if the research is on an exceptionally sensitive or troubling topic, it may be appropriate to consider if parental assent should be sought.
  (iii) Research with children or any vulnerable groups must be conducted with the guidance and supervision of expert intermediaries, and should be conducted in line with relevant external safe-guarding policies.

The Senate has granted authority to the Queen Mary Ethics of Research Committee to establish criteria, processes, and procedures to enact this policy and to grant approval to research according to its terms.

Please see http://connect.qmul.ac.uk/research/ethics-of-research-committee/index.html

Contact

For further advice please contact: Hazel Covill, Secretary to the Research Ethics Committee JRMO, email: h.covill@qmul.ac.uk

Approval

This policy was approved by the QMUL Senate in December 2014

Note: This policy applies only to QMUL

3. Consent to participate in research

The primary purpose of the policy is:

- To ensure any participant taking part in research is a willing participant
- That, in taking part, any research participant is exercising informed consent
- To give guidance to staff on obtaining consent from vulnerable groups.

This Policy should be read and acted upon in conjunction with the Trust's policy on Consent to Examination and Treatment[4].

3.1 Standards for 'All' types of research

Before submitting an application to the Research Ethics Committee, all researchers should:

- Ensure that template information (such as a participant information sheet) is in an intelligible form (responds appropriately to language, literacy and capacity needs). The cost of producing information in these formats should be included in the overall project costing.
- Consider the specific language and cultural needs of the study population. QMUL and BH would particularly encourage researchers to seek advice from local community groups and BH Health Advocacy Service. Failure to engage local ethnic minority groups may have implications for the validity of the research sample;
- Read and adhere to current National Research Ethics Service (NRES) guidelines and templates on writing a participant (patient) information sheet and consent form.

3.2 Procedures for obtaining consent to participate in research

The Health Research Authority (HRA) website contains a range of guidelines on obtaining an individual's consent to participate in health and social care-related research which BH and QMUL researchers must adhere to. They include, but are not limited to, ensuring that:

- Protocol(s) for research involving participants (patients), human tissue, participant data or healthy volunteers are submitted for Research Ethics approval.
- Templates (such as participant information sheets and consent forms) satisfy standards set by the National Research Ethics Service.
- To ensure that research is conducted in an open and transparent manner researchers should:
  - (i) clearly identify any conflict of interest, personal benefit to be gained from the research (including financial) and any involvement with a commercial entity that might constitute a conflict of interest
  - (ii) Ensure that consent covers consent to participate, consent to process personal data and consent to use images gathered during research where this is relevant.
  - (iii) Seek approval for the study from the sponsor and gain local NHS and/or institution permission(s).

Chief Investigators and Principal Investigators leading health and social care-related research at our sites are required to ensure that all research staff working on a research project abide by

[4] Barts Health Policy on Consent to Examination and Treatment, 26 March 2012: http://bartshealthintranet/Policies-and-Guidelines/Documents/Policies-Trust-wide/Consent-for-Treatment-and-Examination.pdf

the standards set by the HRA.

The following applies to all research where it is assumed that the potential participant has capacity to consent.

- Consent for research should always be obtained in writing, be signed and dated by the person taking consent, the participant/their representative and, for health and social care related research, a witness.
- The participant should receive one copy of the signed consent form, a second copy should go on the site file and, where relevant (ie, where the research is health and social care related), a third copy should be kept in the medical notes.
- The researcher should ensure that the original is stored in a secure manner.
- Where participants lack capacity to consent, REC-approved procedures for seeking consent from professional/personal consultees should be followed.
- Written consent should be sought from the participant at the earliest opportunity.
- The best practice procedures for written consent and records storage should be followed.

More information concerning groups requiring Special Consideration is contained in Section 3.5 below).

In order to be able to demonstrate compliance with Good Clinical Practice & Research Governance requirements the researcher must be able to show that:

- The participant was consented by someone fully trained and able to explain the nature of the research, the risks and benefits of taking part and capable of answering any questions the participant may have;
- The version of the consent form and participant information sheet used to obtain consent is the same version approved by the REC;
- The participant had ample time to consider whether to take part in the research;
- Appropriate advocacy or translation arrangements were made available during the consent process and clearly documented. Ideally all participants requiring advocacy or translation should have this provided in person;
- The participant is aware that they may withdraw at any time without their routine care being affected;
- The participant had a contact point for further information about the study;
- Where there were changes to the arrangements for obtaining consent after ethical approval has been granted, these were notified to the Research Ethics Committee that approved the study and the Research Governance and GCP Managers in the JRMO; and
- Participants should not have been offered financial inducements that may have encouraged them to take undue risks. Reimbursement of expenses and moderate inconvenience allowances are of course permitted.

3.3 Research on Human Tissue

The Human Tissue Act (HTA) 2004 regulates the storage and use of human organs and tissues from the living and the removal, storage and use of organs and tissue from the deceased. Certain uses (scheduled purposes) require appropriate consent.

Scheduled purposes include:

- Obtaining scientific or medical information about a person which may be relevant to any other person.
- Research in connection with disorders or the functioning of the human body.

Researchers should be guided by existing published HTA codes of practice. Human tissue is most commonly obtained from:

(a) The participant/donor directly, as part of an ethically approved project.
(b) A licensed tissue bank.
(c) A diagnostic archive.

In the case of (a), the participant/relative must have given informed consent or a DH compliant post mortem form, whichever is appropriate. If, in taking consent, the participant/relative states that there are certain types of research they do not wish the tissue to be used for, researchers must respect this and be able to demonstrate that the end use is not in conflict with the participant/relatives' wishes.

In case of (b) and (c), tissue banks and diagnostic archives will usually only provide tissue to projects with ongoing ethical approval and will ensure that participant/donor information is not available to the researcher.

All research must have ethical approval and specific consent. Both the consent forms and participant information sheet must conform to NRES guidelines.

If it is not feasible to contact participants to obtain consent for use of samples collected at an earlier stage, the REC must confirm that it is acceptable for the research to proceed without it.

Particular care is needed where research involves tissue or organs from the deceased. Consent of relatives must be obtained (see above exceptions). Arrangements must be described for the respectful disposal of material once the research has been completed.

Researchers should ensure that the participant information sheet makes clear which organisation(s) have access to the sample(s). This is particularly important where a commercial organisation is directly involved in the research, or where the samples may be passed on for further research and/or commercial exploitation.

Researchers may not sell samples for profit (in cash or in kind).

3.4 Personal data

Any personal data (including de-identified data) passing outside the European Economic Area (EEA) is subject to Section 8 of The Data Protection Act.

This requires explicit participant consent to the transfer. The participant consent form must contain a section that gives permission for a named investigator to transfer information to a named organisation that is based outside the EEA.

Any personal data must be held in a way that is consistent with the Barts Health Data Protection Policy[5].

3.5 Groups for special consideration

There are several groups of potential participants whose inclusion in research requires special consideration. These include but are not limited to:

[5] Barts Health Data Protection Policy, 10 September 2015: http://bartshealthintranet/Policies-and-Guidelines/Documents/Policies-Trust-wide/Data-Protection.pdf

- Children
- Adults lacking capacity to consent
- Participants in emergency situations

The involvement of frail elderly people, those living in institutions and pregnant women should also be given special consideration.

When planning research involving these populations, researchers should seek advice from the JRMO, BH and QMUL SOPs, all applicable regulations and guidelines and ensure use of guardians, parents, personal, legal and professional representatives, as appropriate.

For all groups consent must still be freely given and based on information which is provided in a form that is understandable to each individual (and/or their legal representative).

Individuals lacking capacity to consent may be included in research only if it relates to their condition and the relevant knowledge could not be gained through research on persons able to consent. Please see the Mental Capacity Act (2006) 6, for further information.

3.6 Monitoring

The JRMO will ensure that all research within BH and QMUL has appropriate ethical approval and that consent for research is being taken as specified in the ethics application through its routine auditing process.

Further Information may be obtained from:

1) Research Governance and GCP Managers, Joint Research Management Office

2) HRA website: www.hra.nhs.uk/

3) Medicines & Healthcare Products Regulatory Agency: www.mhra.gov.uk

Note: This policy applies to both QMUL and BH.

Section B: Assuring the scientific quality of research

4. Review of research including peer review

4.1 Purpose of the Policy

A key component of good research practice is the need for **all** research to be subject to independent review (including peer review of the quality of the research[6]). In this situation "independent" means independent of the research team undertaking the research, not necessarily the department or institution. Similarly, UK law on the conduct of clinical trials requires host and sponsor organisations to ensure that research practice adheres to recognised international standards.

If carried out appropriately, review (including peer review of the quality of the research) addresses the scientific quality and relevance of the research, the capacity of the organisation to conduct the research (i.e. the availability of facilities, staff, equipment or other resources), its resource and financial implications, legal and regulatory compliance and aspects of health and safety. It is, therefore, an important means of ensuring that the organisation knows about research being conducted under its name, which uses its staff, patients and facilities and is satisfied that it is safe, affordable and of good quality.

External peer review of research quality is generally undertaken by research funders and may be used as part of the review process. Ensuring robust internal peer review processes are in place is particularly important for research which is not externally funded.

Evidence of peer review is required as part of the process of obtaining ethical approval for research and is necessary for portfolio adoption.

Failure to obtain a peer review committee's approval for research or falsely claiming that this is in place may constitute research misconduct. Procedures for dealing with this are outlined in policy 22: Misconduct and Complaints.

4.2 Scope

For the purposes of this policy, review includes peer review of the quality of the research; resource and capacity review. In addition, for clinical trials and research involving human subjects, review also includes the quality of the protocol.

The policy applies to all staff conducting research and external staff using BH or QMUL as a base or site for their clinical research.

This policy also includes student research. For non-QMUL or BH students the primary responsibility for the quality of the research lies with the relevant university.

4.3 Summary of the Policy

To ensure that the BH and QMUL have a review process in place which is robust, but also appropriate and proportional, the Policy sets out:

- The levels of review needed for all research.

[6] The Declaration of Helsinki (1996), The Research Governance Framework for Health and Social Care 2001 and revised 2005.

- Guiding principles for establishing committees.
- Reporting mechanisms.

4.4 The Policy

4.4.1 General Approach

All research must undergo review - a peer review of the quality of the research and resource and capacity review to establish the resource and financial implications of the research activity for the institution and department. It is also good practice to assess how the research fits in with departmental research strategies and balanced portfolios. It is the responsibility of the relevant schools, institute or Clinical Academic Group (CAG) to ensure that appropriate review is undertaken.

The purpose of this policy is not to be prescriptive about whether review would best be carried out at the Faculty, Institute, CAG, site, speciality or sub-speciality level, or even across teams/ organisations. It is for staff in each CAG, Institute and Faculty to establish the most appropriate model for themselves. However, accountability for the review and resource and capacity review will remain with the Dean or Director of Research, Insitute Director or the CAG Director of Research.

4.4.2 Review of clinical trials and clinical research involving human subjects

For clinical trials and all clinical research involving human subjects, each CAG, Insitute or School must ensure that, as a minimum, the following reviews are conducted for each study:

- Peer review – reflect the science quality of the project.
- Protocol review – quality of the document and its practical implementation.
- Resource and capacity review – adequate resources exist to conduct the study and that the department has the necessary capacity and infrastructure to ensure research is carried out to an adequate quality level. (Relevant NHS departments including imaging and pharmacy, QMUL labs, external labs, trial support team and/or CTU support, funding).
- The department has robust systems in place to ensure on-going oversight (clinical and administrative) throughout the trial.

4.4.3 Who should review research?

As a minimum, review should be independent of the research team. Best practice for peer review of research is that it should be conducted by individuals external to the organisation. However, it is recognised that for practical purposes this may not be possible and that, in the majority of cases, internal, independent review is sufficient.

Peer review and clinical protocol review should be carried out by those people who are qualified to make a judgment about the scientific quality, relevance and probity of the research and the quality and clarity of the protocol together with the feasibility of its practical implementation.

In undertaking the Resource and Capacity Review, those involved should be able to address the practicalities of undertaking a specific piece of work in the organisation, its cost (including those of all the relevant service and clinical departments inputting to the research) and the capacity of the department or research group to deliver the project.

4.4.4 Proportionality of review

Externally funded research - Research that is externally funded through open competition normally has external scientific peer review conducted by the funders built into the application process. However, these research projects still require a resource and capacity review (as described above). Copies of all review approval documentation (internal and external) must be sent to the JRMO for their records.

This includes commercial and non-commercially funded research.

Own account/internally funded research - It is important that own account and internally funded research is subject to a thorough review, including independent peer review in order to make sure the Trust and QMUL can demonstrate that all its research meets the required standards of quality, probity, financial transparency and that the School/ Institute/ CAG/ Trust site (as applicable) has the required funds to cover all the costs associated with the project.

Student research - Student research and other projects that are short-term and have minimal resource implications should be treated proportionately, with the emphasis on general appropriateness and the impact the research could have on the institution, service delivery and on patients. CAGs, Institute and Schools may wish to consider a fast track form of review for these studies to ensure there is no unnecessary delay in commencement and inform JRMO of any relevant deadlines.

Research in small sub-specialties or small departments - Researchers working in small sub-specialties or small departments where there are limited numbers of people able to provide independent expertise, may need to send their research for external review. However, if researchers choose this route they must:

- Make sure that their ideas are adequately protected (see 4.4.9 below);
- Make the findings of the external reviewer available to the local peer review committee and JRMO.

4.4.5 Establishing Review Committees

- Each School, Institute and CAG and Institute must formally establish a committee to review its research proposals.
- Each committee should formally adopt specific terms of reference. Advice on the content of these can be obtained from the JRMO.
- In addition to this general statement on the purpose of the committees, it is essential that the responsibilities of researchers and the local committee are explicit for each local system and will include an appropriate escalation process.
- Each review committee should formally adopt the standard operating procedures of the JRMO and publicise them to all staff in their areas.
- By way of an escalation process any decisions taken by review committees can be referred upwards to the Joint Clinical Research Board for review.

Adequate administrative support will be essential if committees are to function effectively. Additional guidance on all aspects of establishing Peer Review Committees will be available from the JRMO.

4.4.6 Criteria Used for review

Local review committees can undertake both scientific and resource and capacity reviews. The committee should ensure that the research has been comprehensively assessed in the following areas:

- Study design; Risks and benefits of the study, and potential impact.
- The suitability of monitoring and quality control arrangements.
- The adequacy of the research site.
- Adequacy of resources.
- Current research burden on participant population.
- Suitability of research for the departmental portfolio.

If required, a standard form for peer review is available from the JRMO. If the research has been peer reviewed externally then this should be noted in the appropriate sections of the form, a completed copy of which should be sent to the JRMO.

All research (including own account or locally funded research) should be costed by the JRMO prior to the resource and capacity review to ensure that costs and resource requirements can be assessed by the committee.

It should be noted that for portfolio adoption by the National Institute for Health Research (NIHR), any study funded as part of a major award is required to have additional independent external peer review, for example, clinical trials embedded in major research programme grants, BRU funded projects etc.

4.4.7 Committee Composition

It is important that the committee has a sufficient range of expertise to address all the relevant criteria. Committees are often well placed to judge scientific quality but do not always involve people able to assess the impact on routine clinical work and related services such as Pathology, Pharmacy or Imaging. Failure to address these issues at the outset may lead to problems when the research is underway. An important part of the decision making process will be the affordability of unfunded or part funded research.

4.4.8 Reporting Processes

Internal Reporting

The Chair of each local committee, or their designated deputy, should ensure that staff are aware of the following:

How to send research for peer review, including a named contact person, telephone number and email address. .

- The frequency and dates of meetings.
- The expected turnaround time for applications.
- How researchers will be notified of the results.
- Any special arrangements that may apply.

A report of all the projects the committee has reviewed and their decisions should be sent to both the relevant general manager within the CAG, Institute and/or School at least every quarter and to the Governance Team in JRMO.

The JRMO will advertise the procedures for each committee on the JRMO website and when there are changes, in the R&D News Bulletin.

Further advice on peer review can be obtained from the JRMO's Research Governance and GCP Managers.

4.4.9 Confidentiality Guidance for Research Peer Review

All project outlines or protocols sent for review should be clearly marked as confidential. Protocols and project outlines that are sent outside the Trust or College should only be sent once agreement has been received that the reviewer is willing to carry out the review. If there are any concerns surrounding intellectual property or pending patents, advice regarding confidentiality agreements should be sought from the JRMO or Queen Mary Innovation Ltd **prior** to sending out any documentation.

Note: This policy applies to both QMUL and BH.

5. Public involvement

5.1 Background

> "The NHS aspires to put patients at the heart of everything it does. It should support individuals to promote and manage their own health. NHS services must reflect, and should be coordinated around and tailored to, the needs and preferences of patients, their families and their carers. Patients, with their families and carers, where appropriate, will be involved in and consulted on all decisions about their care and treatment. The NHS will actively encourage feedback from the public, patients and staff, welcome it and use it to improve its services."
>
> "The importance of innovation and medical research is….integral to driving improvements in healthcare services for patients."[7]

What is public involvement in research?

INVOLVE defines public involvement in research as research being carried out '**with**' or '**by**' members of the public rather than '**to**', '**about**' or '**for**' them. This includes, for example, working with research funders to prioritise research, offering advice as members of a project steering group, commenting on and developing research materials, undertaking interviews with research participants.

When using the term '**public**' we include patients, potential patients, carers and people who use health and social care services as well as people from organisations that represent people who use services. Whilst all of us are actual, former or indeed potential users of health and social care services, there is an important distinction to be made between the perspectives of the public and the perspectives of people who have a professional role in health and social care services[8].

Why is public involvement in research important?

A growing body of evidence suggests that public involvement in research can influence the research topics and directions of research, project design and methods, recruitment and data collection, analysis and dissemination. Public involvement can also positively impact on the people involved in the research. The strongest evidence available indicates that public involvement:

- can help increase recruitment to all types of research;
- is of particular value in qualitative research where participants are asked to share their views and experiences;
- is of particular value in clinical trials where it can help to improve trial design and ensure the use of relevant outcome measures;
- Benefits the people involved as well as the research participants.[9]

The involvement of patients and the public in research can empower them, give the research greater credibility and help bring about developments that will lead to more sustainable change. Staff, participants in research, and the public in general can help to ensure that standards are understood and met[10].

The purpose of this policy is to ensure that staff undertaking research, at BH and QMUL:

- Are aware of their responsibilities in involving the public in their research.

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[7] DH (2013) The Handbook to the NHS Constitution
[8] INVOLVE (2012) Briefing Notes for Researchers
[9] INVOLVE (2009) Exploring impact: Public involvement in NHS, public health and social care research
[10] DH (2005) Research Governance Framework for Health and Social Care, second edition

- Are suitably trained, and supported to effectively engage and involve the public in their research.
- Aspire to best practice in the different ways they involve the public in their research.

5.2 Policy

Research and those pursuing it, should respect the diversity of human society and conditions and the multicultural nature of society. Whenever relevant, it should take account of age, disability, gender, sexual orientation, race, culture and religion in its design, undertaking, and reporting. The body of research evidence available to policy makers should reflect the diversity of the population.

Wherever possible clinical research should be pursued with the active involvement of service users and carers, including where appropriate those from hard to reach groups such as the homeless[11].

Service users, carers and participants should be involved, when possible, in the design, conduct, analysis and dissemination of research and also in the strategic direction and setting of priorities.

Once established, the results of clinical research should be disseminated to the research community, trial participants and the general public. Special arrangements should be made to ensure access to information for those with a low level of literacy, English as a second language, or a disability[12]. Members of the public involved in your research will want to ensure that the findings are widely disseminated so they can influence and change practice for the better[13]. Public involvement can help to identify how trial outcomes could be communicated. Public contributors can assist with the production of plain English summaries and facilitate the dissemination of these by providing access to patient groups. The results of the trial can therefore be shared appropriately to ensure that the right people and organisations have been involved.[14] For further information, see Section 7 Dissemination Policy.

Patients and members of the public involved in research should be recompensed in line with established good practice[15].

QMUL and BH should seek input from the appropriate national, local and BH or QMUL based Patient and Public Involvement (PPI) leads, patient or interest groups. Current guidance should be sought and followed on recruitment, training and involvement of users in the activities of individual research groups as well as in QMUL and BH corporate activities, such as Clinical Governance or Modernisation groups. Within BH, advice can be sought from the Engagement & Diffusion Unit, Research Development.

Further advice can be obtained from:

Engagement & Diffusion Unit, Research Development, Barts Health NHS Trust,
Education Centre, Newham University Hospital, Glen Road, London E13 8SL
Tel: 020 7363 8923
Email enquiries: patientsinresearch@bartshealth.nhs.uk
Website: www.bartshealth.nhs.uk/takepart

[11] DH (2005) Research Governance Framework for Health and Social Care, second edition
[12] DH (2000) Research & Development for a First Class Service
[13] INVOLVE (2012) Briefing Notes for Researchers – Disseminating Research
[14] For further information, see Clinical Trials Toolkit Routemap – Dissemination of Results
[15] INVOLVE (2010) Payment for Involvement

Centre for Public Engagement, QMUL
E109, Queens' Building, Mile End Road, London, E1 4NS
Tel: 020 7882 6115
Email enquiries: publicengagement@qmul.ac.uk
Website: www.qmul.ac.uk/publicengagement/

INVOLVE
Wessex House Upper Market Street Eastleigh, Hampshire, SO50 9FD
Tel: 023 8065 1088
Email enquiries: admin@invo.org.uk
Website: www.invo.org.uk

NIHR website: http://www.nihr.ac.uk/

HRA website: http://www.hra.nhs.uk/

Note: This policy applies to both BH and QMUL.

Section C: Research information

6. Project registration

6.1 Background

All NHS organisations in receipt of NHS R&D Support Funding are required to maintain an accurate database of all research that uses NHS staff, patients, premises, equipment or facilities. QMUL as BH's principal collaborating organisation uses a significant level of infrastructure support and research participants including patients from across BH.

BH is also a host site for research led by other partners including pharmaceutical companies, other NHS Trusts and Universities. The purpose of this policy is to ensure that research carried out by BH or QMUL together with other collaborating organisations is recorded comprehensively and is maintained throughout the duration of the study in a way that that promotes:

- Sharing of information across organisations involved in joint research or where a researcher holds more than one contract.
- Maintenance of confidentiality and appropriate handling of sensitive information.
- Monitoring compliance of research with the Research Governance Framework Policy and all applicable research regulations.

Overall responsibility for maintaining an accurate database of research lies with the JRMO. This includes entering data, verifying and cleaning the database.

The JRMO will share activity data with QMUL and other collaborating organisations to promote accurate recording and reporting of research activity across all of its research projects.

BH and QMUL may use projects recorded on the database as a mechanism for undertaking monitoring and/or audits of GCP and / or research governance compliance.

It is the responsibility of all investigators to ensure that the following steps are taken to ensure that their projects are properly registered:

- Comprehensive peer review and institutional review are undertaken;
- Costing is undertaken by the JRMO;
- Ethical approval is sought as appropriate from an NHS REC or QMREC;
- BH indemnity or QMUL insurance is arranged;
- No disclosure of valuable IP has been made;
- MHRA approval is obtained, as appropriate;
- Any additional regulatory approvals are obtained as required;
- Arrangements for tissue sample storage and analysis are in place;
- Data storage and data security arrangements are in place; and
- All project documentation is provided to the JRMO

6.2 At the point of registration

The principal investigator or funder must ensure that the JRMO is aware of aspects of any project that should be regarded as 'confidential'.

The JRMO is notified of research that may be sensitive if publicly disclosed (e.g. where the research uses animals or where the research is likely to lead to the development of

potentially valuable Intellectual Property) and advised of how the research should be recorded.

Where research takes place across more than one site and where BH or QMUL is the sponsor (or acts as a legal representative), it is the responsibility of the Chief Investigator to notify the JRMO of all organisations involved and to obtain the appropriate approval (s) from the JRMO prior to activity taking place at any site.

6.3 Following registration

No project activity may commence until the JRMO has received a full set of study documentation approved by the ethics committee and regulatory authorities (if required). The JRMO will provide the PI with final approval documentation as per the JRMO SOPs.

Changes to a project and project termination should be notified to the JRMO as soon as possible and in accordance with sponsor and/or JRMO SOPs.

- Investigators must update the JRMO during the active stage of the project (e.g. annual reporting requirements, safety reporting, project delays/halts, changes in project details such as amendments, changes to vendors or suppliers or where additional contracts are required etc) as per the JRMO SOPs.
- Investigators must update the JRMO at the close of the project with all closure documentation (e.g. end of trial notifications, publications and archiving arrangements) as per the JRMO SOPs

Note: this policy applies to both BH and QMUL.

7. Dissemination and publication

7.1 Background

The Research Councils UK (RCUK) and the Higher Education Funding Council for England (HEFCE) have issued a joint statement to set out the principles regarding greater open access to published research. This included outlining their shared commitment to maintaining and improving the capacity of the UK research base to undertake research activity of world leading quality, and to ensuring that significant outputs from this activity are made available as widely as possible both within and beyond the research community. [16]

The Research Governance Framework requires public sector organisations to actively disseminate the findings of their work to appropriate public sector, academic and public audiences. In addition, effective dissemination is an important means of raising the profile of an organisation, enhancing the recruiting and retention of staff and improving academic and clinical practice.

This policy should be read in conjunction with Policy 11, Research data management. Its purpose is to ensure that staff undertaking research at QMUL and BH are:

- Aware of their responsibilities in publishing and promoting their research activity
- Suitably trained to effectively transmit information to other public sector, academic professionals, the public in general as well as patients and their advocates; and
- Supported to identify suitable mechanisms for dissemination by relevant QMUL and BH departments.

7.2 The Policy

This policy applies to all research which is led by or involves significant input from QMUL or BH staff, honorary employees, short term appointees and visiting staff using BH patients or the staff, premises or facilities of the two organisations, for their research.

All research active staff, are required to abide by the principles of this policy and guidance on publishing research set out in UK and EU Regulations[17] by professional and funding bodies[18].

Before research is initiated:

- Bids for research funds from income streams held by QMUL, BH or associated charitable, government or commercial organisations, should include a broad dissemination strategy, encouraging quality research to be widely disseminated and freely accessed.

- During the course of a research project, investigators should maintain a list of peer-reviewed publications, presentations and other dissemination outlets e.g. briefing papers for commissioners or service managers and make this available to the JRMO in an appropriate electronic format if required; and

- To avoid disputes over attribution of academic credit, it is suggested that, at an early

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[16] For detailed information regarding this please see the RCUK website www.rcuk.ac.uk

[17] Medicines for Human Use (Clinical Trials) Regulations, 2004 (and all its amendments) and EU Directive 2001/20/EC & GCP Directive 2005/28/EC and the Data Protection Act, 1998.

[18] GMC Good practice in research and Consent to research (2010)
Committee on Publication Ethics (COPE) Guidelines on Good Publication Practice

stage, it should be agreed who will be credited as authors, contributors or otherwise acknowledged in the publication. This should, were possible, be clearly documented in the project protocol or outline. Special attention should be given to external collaborators and any funder acknowledgments.

Upon completion of the project:

- Investigators should report results in a way that is transparent and open to audit. Researchers will normally produce publications in academic journals. However, QMUL and BH seek to encourage a broader approach to dissemination that includes dissemination:
    - Within the organisations
    - To professional audiences
    - Of appropriate findings to commissioners and / or service managers
    - To patients, carers or members of the public taking part in the research
    - Of information to the wider general public

- Investigators may seek advice from QMUL or BH Communication Departments on the most effective media to use including language, format and style. Information for patients in particular must take account of the language and literacy needs of the local population. It is important to ensure that participants are informed according to plans described in regulatory approved documentation. Advice may also be sought from the Patient Advice and Liaison Service on these issues.

- For clinical results, particular consideration should be given to the dissemination of adverse findings to participants, those responsible for their care, the research sponsor, funding agencies and other organisations with a remit for public safety such as the Medicines and Healthcare Products Regulatory Agency. All efforts should be made to ensure that patients are informed of results before dissemination to the popular media, particularly where there are clinical implications.

- Dissemination strategies must not breach confidentiality agreements and contractual terms where research is externally funded. However, QMUL and BH would normally expect that external contracts do not unnecessarily restrict the organisations publication rights. In addition, Contracts and Costings officers and investigators should ensure that the potential to protect and exploit intellectual property is not compromised by dissemination plans. Such plans must allow for publication to be delayed allowing time for the filing of patent applications or for other forms of protection to be put in place. For advice on Intellectual Property issues investigators should contact the Innovation and Enterprise Unit at QMUL.

- When disseminating research findings researchers should ensure that details of individual participants are not disclosed, unless the participant has given explicit prior consent.

- Research active staff should ensure that claims of authorship are justified. Where publications involve more than one author, the list of authors must conform to accepted good practice i.e. authorship should be in line with the degree of input to the paper and the project upon which it is based. Conflicts of interest (i.e. those which, when revealed later, would make a reasonable reader feel misled or deceived) must be declared to editors by researchers, authors and reviewers.[19]

- In relation to citations, researchers should ensure that they appropriately reference

[19] GMC Conflicts of interest - guidance for doctors September 2008, QMUL - Standards of Business Conduct , Barts Health NHS Trust - Standards of Business Conduct (Including declaration of interest)

their employer in any publication. QMUL and BH staff must adhere to the Instructional Citation policies (see 8 below).

- Participants have an expectation that they will be given access to the results of a study and sponsors or investigators should normally provide them. Sponsors or chief investigators are expected to explain how participants will be able to access this information when it does become available and when to expect this. This information can be communicated to participants in many different ways and this is a decision for the sponsor or the chief investigator. Study results could be communicated by:

    - post in a letter or newsletter
    - email
    - DVD
    - Website

Source: http://www.hra.nhs.uk/documents/2015/03/guidance-end-study-pis-vs-4-0-16th-march-2015.pdf

7.3 Publication

The JRMO should be notified of any outputs of the research such as guidelines, publications, presentation, changes in service delivery etc. prior to external submission or presentation.

In the event that research misconduct or data integrity concerns have been raised, the JRMO, as sponsor, with senior management of the affected organisation, reserves the right to review, request a hold on publication submission or to refuse permission to publish.

Further information can be obtained from:
Committee on Publication Ethics
BMJ Publishing Group
BMA House, Tavistock Square, WC1H 7JR

Tel:	020 7383 6602
Website:	www.publicationethics.org.uk
Email enquiries:	cope@bmjgroup.com

Note: This policy applies to both QMUL and BH.

8. Citation

This policy has been developed in response to the need to develop a standard citation policy for research publications and grant applications as well as the dissemination of research findings. It builds on a policy first adopted by QMUL for RAE 2008. This was reinforced in October 2011 for REF 2014, with updates in August 2013, when Queen Mary University of London was adopted as the institution's legal name, and in December 2013 to amend the arrangements for monitoring and follow-up action. It is equally relevant that BH employees adopt a standard citation policy in the light of BH's merger in 2012 and subsequent legacy and identity issue.

It is important for our continuing success that the use of the relevant organisation's correct name is consistently used, in order that all citations to the work of our researchers are recognised, and more generally so that all of the contributions to the reputation of the institution by our researchers combine effectively.

8.1 Acknowledging QMUL and BH

In all public events, presentations and debates involving staff discussing work undertaken as an employee of QMUL or BH, participants must make clear that they work for either:

Queen Mary University of London

Or:

Barts Health NHS Trust

Such activities might include attendance at conferences and seminars, TV and radio interviews, articles and quotes for newspapers, posters and event notices, online communications and debates etc. It is crucial that all research and academic debate in whatever form undertaken by staff is associated with the name Queen Mary University of London or Barts Health NHS Trust, as applicable. In all correspondence, email or otherwise, concerning media appearances, public engagement or associated activities, staff must use a signature that makes it clear that they work for either Queen Mary University of London or Barts Health NHS Trust, as applicable. This includes ensuring that Queen Mary University of London and/ or Barts Health NHS Trust are clearly visible on websites, email addresses and signatures and business cards.

While other affiliations (schools, faculties, research institutes, centres, etc.) may be included, QMUL or BH must appear in a prominent position.

8.2 QMUL-specific policy

8.2.1 Citing Queen Mary for research purposes

Similarly, all research publications and outputs by QMUL employees must make it clear that they work for QMUL.

The policy for citing the name of the university in research publications and grant applications applies to all academic and research staff (including honorary staff) and to students whose research outputs are the result of research undertaken and funded through grants awarded to QMUL, and via the use of QMUL resources and facilities. It is not acceptable to drop the QMUL name because the affiliation is considered too long.

How to cite Queen Mary University of London for research purposes

Research outputs by QM authors are indexed in Web of Science under more than thirty different institutional names. ThomsonReuters, the publisher of Web of Science, reported that the comma previously used in the name of the university (Queen Mary, University of London) added to the problem by splitting the name into two parts. It states unequivocally: "authors must present their addresses as Queen Mary University of London without the comma. "

The use of impact case studies for REF makes it similarly crucial that the University's name is associated with the work of its academic staff in the public arena. The consistent use of the name is essential if all relevant research outputs and grants are to be credited to our Units of Assessment. This will, in turn, ensure that QMUL is able to maximise its academic reputation as well as the financial rewards of REF and other forms of success.

For the purposes of research publications, therefore, researchers must ensure that you do not use a comma after Queen Mary. The name must be cited as:

Queen Mary University of London

This title must be used as the institutional address on all forms of research outputs and grant applications, irrespective of where the affiliation appears.

It should be recorded as near the beginning of the affiliation as possible to maximise citation impact. It will be the responsibility of each researcher to ensure that the affiliation details are correctly recorded.

Examples of acceptable citations:

- Researcher name, Queen Mary University of London
- Researcher name, Barts Cancer Institute, Queen Mary University of London
- Researcher name, School of Physics and Astronomy, Queen Mary University of London, Mile End Road, London E1 4NS
- Researcher name, Blizard Institute, Barts & The London School of Medicine and Dentistry, Queen Mary University of London, Turner Street, London E1 2AD

It is recognised that for some publications, for example, those produced by large consortia governed by contracts, this change may involve external negotiation: those affected should contact Emma Bull, Director of Library Services, and give details of the expected timescale for the change.

Researchers should recognise that not following this policy will damage our ability to maximise our return to the REF and other monitoring exercises.

8.2.2 Monitoring

Because there are significant costs to the university (both in terms of REF results, reputation and financial outcomes) of staff failing to follow this policy, QMSE has asked the Director of Library Services to monitor 'pub lists' and other sources to ensure that staff use the appropriate citation format. The Joint Research Management Office will not allow grants to be processed if they do not follow this policy. The Communication team will be monitoring the on-line and press environment to note how QMUL academics are identifying their affiliation.

Staff who do not consistently identify themselves as working for Queen Mary University of London in public presentations or use the citation policy described above, will be reminded of this policy in a letter, copied to their Head of Institute or School and the faculty Vice-Principal and Executive Dean. In the case of persistent non-compliance, the faculty VP and Executive Deans may impose a financial penalty on the relevant school or institute.

There are potentially significant costs to QMUL if research appears under a range of different institution names, as this affects citation data and hence potentially REF results, reputation etc. Given the exceptional importance of this policy we expect all schools, institutes and professional services to take the necessary steps to support staff in promoting their affiliation with their employer.

Contact for questions about this policy

Please contact the Library Research Support team at
scholarlycommunications@qmul.ac.uk

Approval

This policy was approved by QMUL's Senate on 5 December 2013.

8.3 BH-specific policy

8.3.1 Citing BH for research purposes

Similarly, all research activity undertaken by BH and QMUL employees must make it clear that they work for Barts Health NHS Trust.

The policy for citing the name of Barts Health NHS Trust in research publications and grant applications applies to all BH staff (including honorary staff). It is not acceptable to drop the Barts Health NHS Trust name because the affiliation is considered too long.

How to cite Barts Health NHS Trust for research purposes

The consistent use of the name is essential if all relevant research outputs and grants are to be credited to BH which will ensure that it is able to maximise its reputation for research and clinical excellence.

For the purposes of research publications the name must be cited as:

Barts Health NHS Trust

This title must be used as the institutional address on all forms of research outputs and grant applications, irrespective of where the affiliation appears.

It should be recorded as near the beginning of the affiliation as possible to maximise citation impact. It will be the responsibility of each researcher to ensure that the affiliation details are correctly recorded.

Examples of acceptable affiliation:

- Joe Bloggs, Barts Health NHS Trust
- Jane Bloggs, Communications Manager, Barts Health NHS Trust
- Bo Wang, Cardiovascular Services, Barts Health NHS Trust

It is recognised that for some publications, for example, those produced by large consortia governed by contracts, our preferred citation format may involve some negotiation with external bodies, both funders of research, particularly the National Institute for Health Research and other partners.

8.3.2 Monitoring

Staff who do not consistently identify themselves as working for Barts Health NHS Trust in public presentations or use the citation policy described above, will be reminded of this policy in a letter, copied to their CAG Group Director and BH's Medical Director. Persistent non-compliance may result in further action being taken by BH.

Note: This policy applies to QMUL and BH as indicated.

9. Use of participant information for research

9.1 Background

The Data Protection Act[20], Caldicott Report[21], Research Governance Framework[22], ICH-GCP[23], funding and professional bodies[24] and National Information Governance Board [25] have all issued guidance on how patient information for the purposes of research should be gathered, handled, stored and disclosed.

The purpose of this policy is to ensure that BH and QMUL staff undertaking research that uses research participant information, are aware of their responsibilities with regard to use of existing medical records, as well as creation of new hard copy or electronic patient records for research.

9.2 The Policy

This policy covers the following areas:

(i) Use of existing records for the purpose of identifying or enrolling participants in a study.
(ii) Obtaining and storing participant data for research, or retrospective note-based studies.
(iii) Compilation, handling, audit and storage of research documentation utilised for research.
(iv) New or existing electronic files of research participant information for the purposes of research.

General Guidelines

- Data must be kept and shared in keeping with the details supplied in the original ethics application.

- Organisations outside BH, including QMUL, wishing to access personally identifiable data for the purposes of research must comply with BH Data Protection Policy Annex on 3rd Party Access[26].

- Participant information used for research whether it is existing records or records created purely for the purposes of research must conform to accepted standards laid out by the National Information Governance Board (NIGB), EU and UK law, professional bodies and funding organisations regulations. All staff must make sure that they are aware of these standards before commencing a research project.

- Costs of providing a Medical Records and Archiving Service must be included in the research project costing for externally funded research.

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[20] Data Protection Act, 1998
[21] Caldicott Committee (1997) Report on the Review of Patient - Identifiable Information
[22] Department of Health (2004) Research Governance Framework for Health & Social Care and The Department of Health (2003) Code of Confidentiality.
[23] International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use, 1996.
[24] MRC Guidelines for Good Clinical Practice in Clinical Trials, 1998. Safeguarding Good Scientific Practice (1998) Joint Statement by the Director General of the Research.
[25] National Information Governance Board http://www.nigb.nhs.uk/
[26] Public Interest Disclosure Act, 1998.

- The confidentiality of records that could identify individual participants should be protected. Where data is needed for the purposes of research investigators should:
    - Seek consent for disclosure wherever practicable.
    - De-identify data where possible.
    - Keep disclosures to a minimum.

- Records made for one purpose, such as the provision of care, should not usually be disclosed for another purpose without the patient's consent. Investigators asked to supply participant information for research should assure themselves that the patient has given express consent wherever this is practicable.

- Where it is not practical for the person that holds the records to obtain consent or to de-identify records, data may be supplied for research. However, participants must be informed that:

    - Their records may be disclosed to persons outside the team which provided their care.
    - The purpose and extent of the disclosure.
    - That the person given access to the records is bound by confidentiality.
    - That they have a right to object and their objection will be respected unless there is significant public interest to be served.

- Where a clinician or an academic controls access to personal information on research participants they must not allow access to any staff member unless:

    - The person has been properly trained.
    - Appropriate ethical and BH/QMUL approval has been obtained.
    - The person is subject to a duty of confidentiality.

- Records used for research are NOT the property of the Investigator or researcher but the property of the sponsor or institution. They must, therefore, be stored, handled and reported in a way that means they are accessible to:

    - Other clinicians responsible for care of the patient.
    - Monitors from approved regulatory, funding and sponsor organisations.
    - Other academics or academic organisations who, under funding body rules, have a use for the base data collated by QMUL or BH researchers for future research projects[27].

- All records used for research must conform to The National Health Service Litigation Agency (NHSLA) Risk Management Standards[28], BH and QMUL Data Security and Management Policies.

- All projects Submitted to JRMO will be reviewed to ensure consistency with the Data Protection Act and local policy requirements[29].

- Researchers must conform to BH and QMUL Data protection policies and should seek guidance, when required, from the JRMO and BH and QMUL Information governance teams.

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[27] Research Councils UK (RCUK) policy on Research data-sharing – information can be found at http://www.rcuk.ac.uk/research/Pages/DataPolicy.aspx. An example of a specific policy is the MRC policy on Data Sharing September 2011

[28] NHSLA Risk Management Standards 2012-13, Organisational Policies and Procedures.

[29] Barts Health NHS Trust Data Protection Policy May 2009
QMUL Data Protection Policy November 2009

Use of BH Medical Records Service

- Medical Records will only be supplied for research that has appropriate ethical and BH/QMUL approval, following completion of the Request for Access to Patient records form.

- All research which uses BH patient records or includes volunteers must be formally registered with BH JRMO for internal review and the subsequent approvals process.

- All requests for records for research should supply the name & contact details of a person who will be responsible for their safekeeping.

- Research staff must give adequate notice of the need for records to be traced and pulled, particularly where large numbers of records are involved. Records should then be viewed in a secure area.

- Where a large number of records are required, they should be requested in batches to avoid compromising access to patient data for the purposes of service or audit.

- Records must be returned to the Health Records Department as soon as possible and NOT passed onto other staff or departments without appropriate documentation being completed which will allow onward tracing.

- Patients have the right to expect that staff will adhere to approved standards for maintaining confidentiality. Records must be stored securely during their use in research and not left in areas where there is public access.

Note: This policy applies to both BH and QMUL.

Section D: Minimising risk in research and development activities

10. Minimising risk

10.1 Background

A significant volume of research activity is undertaken by QMUL and BH, funded through a variety of external and internal sources. All studies carry a definable level of risk and must be adequately managed to ensure that these risks are minimised.

The main risk categories are as follows:

- Clinical risk
- Product risk
- Employment risk
- Contractual risk
- Asset risk
- Financial risk
- Reputational risk
- Investigator risk

Detailed policies on each of the areas set out below are contained in various sections of this core research management policies document. Reference will be made to each relevant policy. By adhering to QMUL and BH policies, staff will minimise the risks associated with carrying out their research.

10.2 Policy

Staff undertaking research in QMUL and BH will adhere to national legislation and regulatory frameworks and the relevant QMUL and BH research management policies, to ensure that the risks associated with undertaking research are minimised.

10.3 Regulatory Compliance

Staff will comply with local and national regulations before commencing any research activity in QMUL and BH, ensuring also that their managerial procedures are adhered to. This will include:

- Obtaining external or internal Ethical Approval – See policy numbers 1 and 2.
- Obtaining regulatory approval from an appropriate regulatory body e.g. The Medicinal and Healthcare products Regulatory Agency.
- Adherence to Good Clinical Practice or Good Laboratory practice and the Declaration of Helsinki when undertaking research.
- Adherence to the published Research Governance Framework for Health and Social Care.
- Compliance with the Human Tissue Act.
- Compliance with the Data Protection Act.
- Information Governance policies and procedures of QMUL and BH and other relevant regulations.
- Adherence to QMUL and BH policy with regard to the management of research and development activities in the organisations.

10.4 Clinical Risk

Clinical risk is a generic term that covers a wide range of clinical and related activities. Investigators are required, when undertaking clinical activities as part of their research, to adhere to the appropriate BH and QMUL policies and relevant national and local clinical

guidelines. Access to these policies is via the BH or QMUL's web sites. Particular attention should be paid to the following core policies:

- Health and Safety policies of BH and QMUL
- Complaints policies of the BH and QMUL
- Policies relating to Clinical Studies
- Risk Management Strategy & Policy (COR/POL/0042015-001)
- Adverse Incidents Policy (COR/POL/041/2014-001)

10.5 Product Risk

Staff will ensure that the risks associated with the use of experimental products in research are minimised by:

- Adhering to the Indemnity Policy – Policy Number 15
- Complying with MHRA regulations and adhering to the safe handling of medicines in clinical trials Policy Number 13 and the use of medical devices in research Policy Number 14
- Ensuring that the value to any patients or volunteer subjects participating in research projects outweighs the personal risks surrounding such participation. This issue should be addressed during the Peer Review Process.

10.6 Employment Risk

Investigators leading research projects, together with other staff who may be involved in the appointment of other staff with a research remit, must adhere to the respective organisational policies on HR arrangements for research active staff.

10.7 Contractual Risks

To control the risks associated with entering research contracts with external research sponsors and collaborating partner organisations, staff involved in research shall pass the responsibility for all contractual matters relating to research to the Joint Research Management Office, who will negotiate contract terms, prices and arrange for contracts to be signed by an authorised signatory. Failure by staff to adhere to the policies covering agreement with external sponsors of research could be regarded as research misconduct.

10.8 Asset Risk

QMUL and BH have, over many years, built up considerable expertise, knowledge and know-how in many scientific fields. This resource, together with the facilities they have at their disposal, constitutes a valuable asset base upon which the organisation's research strategies and plans are developed. All employees involved in research have a duty to ensure that the assets of QMUL and the BH are protected, in particular those Intellectual Property assets that may have future commercial value.

To minimise the risk of external organisations taking unfair advantage of the communication and dissemination activities that are necessary facets of the research process, investigators are required to adhere to the policies set out in Policy 7, Dissemination and publication and Policy 16, Identification and protection of Intellectual Property.

Investigators must contact the Joint Research Management Office before entering any arrangement with external research collaborators or funders

10.9 Financial risk

QMUL and BH must ensure that research is not conducted which could lead to unfunded, unreasonable costs being incurred by either organisation. Commercially funded research must be fully funded and not subsidised in any way by BH or QMUL. To minimise financial risks Investigators must ensure that their research costs have been agreed by the JRMO as per the relevant SOPs and adhere to the following policies: Policy 18, Costing research and Policy 19, on externally supported R&D Pricing.

10.10 Investigator risk

The investigator and all staff working on a research project must adhere to the approved protocol to ensure that they are compliant with all regulations pertaining to research and to ensure that they are fully indemnified. Chief Investigators of CTIMPs are required to attend the mandatory CI training courses run by the JRMO and ensure that their own knowledge of the regulatory frameworks for research are adequate, by undertaking regular training updates in GCP. Where an investigator is made aware of any breaches in compliance to the protocol they must inform the JRMO as per the relevant published JRMO SOPs.

Where a study is single site the CI and PI will be the same person unless there are agreed exceptional circumstances. CI and PIs must be experienced in the therapeutic area of the study and in clinical research. CIs or PIs who lack relevant experience in clinical research may still be selected to perform the role of CI or PI; however, this must be agreed, in writing, by the sponsor, who may appoint an experienced individual to support or mentor the CI or PI for the duration of the study. This will facilitate the development of the research workforce.

10.11 Reputational risk

The investigator and all staff working on a research project should ensure that their activities do not lead to reputational damage for the BH, QMUL or the sponsor organisation. This is mitigated by ensuring that the study is compliant with the UK regulations governing research, the protocol and the policies of each organisation and the JRMO SOPs.

10.12 Responsibility for Minimising Risk in relation to Research Activities

The Investigator and all staff working on a research project or programme of research have both individual and collective duties to ensure that studies are conducted in accordance with good academic practice in research, Good Clinical Practice, Good laboratory Practice, national regulations and QMUL and BH standing orders and corporate policies. Clinical Academic Group Directors, Institute Directors, faculty managers and the Joint Research Management Office are charged with a duty to ensure that staff adhere to this regulatory framework

Note: This policy applies to both BH and QMUL.

11. Research data management at QMUL

11.1 Background

A 2008 HEFCE-funded report defines research data as "the evidence base on which academic researchers build their analytic or other work." Data management, including planning for long-term storage and sharing, is an increasingly important aspect of the UK Research funding environment. Most grant applications for research which will generate digital data sets require a data management plan that meets the 2011 Research Councils UK (RCUK) policy; this states that: 'Publicly funded research data are a public good, produced in the public interest, which should be made openly available with as few restrictions as possible in a timely and responsible manner that does not harm intellectual property:' http://www.rcuk.ac.uk/research/Pages/DataPolicy.aspx.

As of May 2012, RCUK required all funded universities to have a data management policy and road map in place that will be fully implemented by 2015 to meet their expectations for data sharing, as follows:

- Publicly funded research data should be made openly available in a timely manner.
- Data with acknowledged long term value should be made accessible.
- RCUK recognises that there are legal, ethical and commercial constraints on release of research data. To ensure that the research process is not damaged by inappropriate release of data, research organisation policies and practices should ensure that these are considered at all stages in the research process.
- Research Council funded work may be entitled to a limited period of privileged use of the data.

A summary of funder data management/sharing requirements can be found here: http://www.dcc.ac.uk/resources/data-management-plans/funders-requirements

BH supports this stance and works with QMUL to manage its research data in ways that accord with the external policy recommendations and uphold data sharing expectations. Due to the close ties of QMUL and BH researchers much of BH's research data will be held on QMUL systems and so QMUL open access guidelines and QMN IT data management requirements are directly relevant; no stand-alone Trust guidance or information needs exist.

11.2 Research Data Access and Management Policy

(i) QMUL and BH are committed to the general principle of Open Access to research, including to research data[30] within the necessary constraints of any funder, legal and ethical requirements, and following QMUL policies, guidelines and standards.

(ii) Due to the particular concerns around access to medical-related data, access to data that is associated with medical research will be governed by the relevant funder's policies on data sharing. If a funder does not have such a policy, then the MRC's policy on data-sharing should be the default policy[31].

[30] QMUL and BH research data here refers to the final forms of information which are essential to the understanding of the published or otherwise publicly available final research output that represents the completion of a well-defined research project. This information is generated by QM and BH researchers for the purposes of the research project, for example via experimentation, observation or interview. It may include samples and related material used or created in the course of the research. Published materials, bibliographies, and data acquired from third parties (generated outside QM and/or BH) are not included in this definition.

[31] http://www.mrc.ac.uk/Ourresearch/Ethicsresearchguidance/datasharing/Policy/index.htm

(iii) Where reasonably practicable, publicly funded research data should be made available for access, subject to such conditions as are necessary to ensure compliance with legal, data protection, ethical, confidentiality, IP protection, and security or funder obligations.

(iv) Data identified for open access will be offered for deposit either in a QMUL or an appropriate external repository, in accordance with relevant standards and community best practice, which may be determined by the area of research activity.

(v) Data must be retained intact in an appropriate format and storage facility according to funder requirements and consonant with any data management plans approved as part of any funding.

(vi) The rights of researchers to the exclusive use of research data that they generate as part of a well-defined research project will be protected up until the point of publication or public availability.

(vii) Where data is made available on request rather than via straightforward open access the rationale for this must be made public and such availability should not be unreasonably withheld.

(viii) Data arising from research involving human subjects can only be made accessible if those subjects give their informed consent in advance in writing for the future public release of their data, with clear and study- specific explanations of how the data will be anonymised so that it will not be possible for those in receipt of the data to identify any individuals. Where it has been determined that it would be inappropriate to make such data accessible, for example because it might lead to identification of research subjects or because seeking consent would make it unlikely that subjects would participate in the research, then the data will remain confidential.

(ix) For research collaborations, any open access arrangements can only take place with the agreement of all research partners.

(x) Where retention is not specified as a condition of funding, data storage and disposal will be determined by the nature of the research activity and would normally be retained for a period of at least 10 years for non-clinical and at least 20 years for all clinical based activities from the date of any publication which is based upon it, as specified in the QMUL and BH Records Retention schedules.

(xi) Protocols for research in which data will be generated or reused should include data management plans that explicitly address data capture, management, integrity, confidentiality, retention, sharing and publication. These plans will be retained by QMUL and BH, as appropriate, to guide future management of the data.

(xii) The Principal Investigator, or most senior QMUL researcher, in a research project, has responsibility for ensuring that research data management requirements are observed during a research project or programme that they are undertaking.

(xiii) Those responsible for research staff and students should ensure that researchers in their areas are aware of this policy and any associated guidelines and procedures.

(xiv) All researchers are expected to familiarise themselves with and act in accordance with this and other QMUL and BH policies relating to research practice. This information will be made accessible from the QMUL and/ or BH research webpages, both external and internal.

(xv) QMUL and BH will provide their staff with advice, training and support regarding research data management.

(xvi) Any queries on the application of this policy should be directed to the Vice-Principal (Research) or to JRMO's GCP team.

(xvii) Appeals against the withholding of data may be made in writing to the Vice-Principal (Research), or to the JRMO's GCP team who will review the case from the researcher or their representative for withholding data, and the appeal case, in the light of this policy and other relevant policies, and make a final decision

11.3 Further information

For information about open access please see the Queen Mary Library research webpages http://www.library.qmul.ac.uk/openaccess

The *QMUL Guidelines on Open Access* are available at http://www.library.qmul.ac.uk/sites/www.library.qmul.ac.uk/files/users/user15/OA__Principles%20&%20Guidance.pdf

For information about IT Services support for IT resourcing and data management requirements please see the ITS webpages at http://www.itstrategy.its.qmul.ac.uk/research/researchdatamanagement/

Note: This policy applies to both QMUL and BH

12. Clinical trial compensation

12.1 Background

Clinical trials and other research studies undertaken by employees of QMUL or BH may be undertaken at the instigation of commercial organisations or non-commercial external funders, or they may be unfunded. Where trials are funded by a company, it is accepted practice for the company to offer compensation to patients or healthy subjects who participate, if they are harmed through some fault of the manufacturer or for other reasons not attributable to the negligence of the investigator. In such circumstances, the offer of compensation will be made in accordance with a standard procedure of independent evaluation.

At present, a trial subject who suffers harm as a result of participation in a non-company-funded (e.g. charity-supported) or unfunded study will only be entitled to compensation if they can prove negligence on the part of the investigator or the clinical staff or the manufacturer of a product used. They must, therefore, prove not only the existence of fault but who or what was at fault.

It is generally thought that where a subject is harmed as a result of participation in a trial, the prospect of compensation should not depend on whether the trial happens to be company-sponsored or if there is evidence of negligence.

This document sets out QMUL and BH's policy in relation to compensation payments. It sets out applicable criteria and procedure for making compensation payments to those subjects injured in non-company sponsored trials for which there is no alternative equivalent compensation available, or in company-sponsored trials where injury results from the negligence or other fault of the investigators.

12.2 The Policy

For the purpose of this policy, Trial Subject means:

a) A patient, i.e. an individual, whose participation in piece of research derives from either:
   - Having sought or accepted medical care within BH primarily for treatment of a condition, the investigation of which is the subject of the clinical trial.
   - Having been selected from the general population because of known or suspected abnormality

b) A healthy volunteer, i.e. an individual, who is generally healthy and does not suffer from the condition expected to be modified by the trial intervention.

c) A child in utero - a child subsequently born alive whose mother was a trial subject while the child was in utero.

While this policy at a minimum also would apply to non-patient volunteers (i.e. "healthy volunteers"), arrangements for this category of Trial Subjects are receiving further considerations.

All research studies must first be submitted to and approved by an appropriate ethics Committee or other relevant ethics committee and Joint Research Management Office. Failure to obtain such approval, or disregard of any conditions for an approval, would be a breach of the investigator's terms of employment within QMUL or BH. Further, the investigator could bear personal responsibility for any harm resulting to a patient.

12.3 Coverage

QMUL or BH will pay compensation to trial subjects suffering bodily injury in accordance with this policy.

Compensation will be paid when, on balance of probabilities, the injury was attributable to the administration of a medicinal product or device under trial or any clinical trial intervention or procedure provided for by the protocol that would not have occurred but for the inclusion of the patient in the trial.

Where a trial design includes pregnant women, the principles of compensation under these Guidelines will apply to injuries caused to a mother or to her child in utero. However, since strict criteria are laid down by the NRES Research Ethics Committee for the exclusion of pregnant women from clinical trials in general, compensation will be paid in the event of injury to a child in utero only where the mother's participation in such an excluding trial has been non-negligent on her part.

Compensation will not be paid for temporary minor pain or discomfort.

Where there is an adverse reaction to a medicinal product or device under trial and injury is caused by a procedure adopted to deal with the adverse reaction, compensation will be paid for such injury as if it was caused directly by the medicinal product or device under trial.

Neither the fact that the adverse reaction causing the injury was foreseeable or predictable, nor the fact that the trial subject has freely consented (whether in writing or otherwise) to participate in the trial, should exclude a trial subject from consideration for compensation under this policy although compensation may be abated or excluded in the light of the factors described below in section 12.4.

This policy applies to injury caused to patients and healthy volunteers partaking in clinical trials involving unlicensed medicinal products or devices who are not protected by a similar policy offered by any external sponsor of the trial.

Compensation will also be paid for injury caused by licensed or non-licensed products administered to the trial subject for the purpose of comparison with the product under trial.

12.4 Limitations

Compensation will not be paid:

- For the failure of a medicinal product, device, technique or procedure to benefit a patient
- To patient receiving placebo in consideration of its failure to provide a therapeutic benefit
- To the extent that the injury has arisen (or it should be abated as the case may be):
    - Through the wrongful act of default or a third party for whom QMUL or BH is not responsible (e.g. the patient's own doctor); or
    - Through contributory negligence by the trial subject.

The maximum amount of compensation payable under this policy will be the maximum ex gratia payment permitted by QMUL's insurance policy or, in the case of BH, The Department of Health national insurance provisions.

The undertaking given by QMUL and BH extends to injury arising (at whatever time) from all administrations, clinical interventions or procedures occurring during the course of the trial but not to treatment extended beyond the end of the trial at the instigation of the investigator. The use of unlicensed products beyond the trial period or on a named patient basis is wholly

the responsibility of the treating doctor. Doctors should notify their protection society of their use of unlicensed products.

12.5 Investigators Liability

Where the cause of an adverse reaction or injury is attributed wholly or partly to a significant departure from the protocol as approved by the NRES Ethics Committee and QMUL or BH, either organisation, in respect of its liability to compensate the trial subject, shall be entitled to claim indemnity to the appropriate extent from the investigator(s) responsible. For this reason investigators are required to maintain appropriate professional indemnity insurance.

12.6 Assessment of Compensation

Subject always to any overriding financial limit imposed on QMUL or BH, the amount of compensation should be appropriate to the nature, severity and persistence of the injury and should in general terms be consistent with the quantum of damages commonly awarded for similar injuries by an English court in cases where legal liability is admitted.

Compensation may be abated, or in certain circumstances excluded, in the light of the following factors:

a) The seriousness of the disease or condition being treated.
b) The risks and benefits of established treatments.
c) The known or suspected risks and benefits of the trial medicine or device.
d) The information and warning given to the patient as to (a) – (c) above, in the knowledge of which he or she has given consent.

Where QMUL or BH have agreed in principle to compensation being paid but the amount offered under clause 12.4 is not acceptable to the trial subject, the question may, if the trial subject agrees, be submitted for the decision of an independent arbitrator accepted by both parties, and failing such appointment, to be appointed by the President of the Law Society.

12.7 Procedure and Claims

An investigator undertaking a non company-sponsored trial should make it clear to participating trial subjects that the trial is being conducted in accordance with either BH or QMUL policy.

The management of claims will be decided, on a case by case basis, between QMUL and BH, with due regard to the employment status of the investigator, any contractual arrangements with external funders, honorary contract considerations and insurance coverage. Once agreement has been reached, and where it is possible, one organisation will conduct the procedures involved in examining and settling claims.

Claims pursuant to this policy should be made by the trial subject to BH for patient based studies, or the most appropriate organisation in the case of patient volunteer studies, setting out details of the nature and background of the claim and are conditional upon the trial subject providing, on request, an authority for BH or QMUL to review any medical records relevant to the claim. QMUL or BH should consider the claim expeditiously.

Trial subjects should be required to accept that any payment made under the policy is in full settlement of their claims.

The fact that QMUL or BH has agreed to abide by this policy does not affect the right of a trial subject to pursue a legal remedy in respect of injury alleged to have been suffered as a result of participation. Nevertheless, it is hoped that by adopting this policy the organisations will be seen to deal fairly with trial subjects and will avoid litigation with its attendant expense, publicity and uncertain outcome.

Where relevant, the basic principles and procedures described in BH's Policy for handling of Clinical Negligence and Personal Injury Claims will apply to this clinical trials compensation policy except where the procedures are in conflict, in which case the wording of this clinical trials compensation policy will take precedence.

In providing financial compensation in accordance with this policy QMUL and BH accept the need for an expeditious settlement and will make every effort to complete the necessary investigations as a matter of urgency.

Note: This policy applies to both BH and QMUL.

13. Safe and secure handling of medicines in clinical trials

13.1 Background

The purpose of this policy is to ensure that BH and QMUL comply with the relevant guidelines for the safe and secure handling of clinical trial medication.[32]

This policy applies to all drug trials that involve BH patients and healthy volunteer studies.

The ordering, storage and handling of clinical trial medication must comply with BH policies on the safe and secure handling of medicines. BH's Pharmacy Department must be involved at an early stage of all clinical trials that involve the use of medicines.

Where a trial does not use regular systems of purchasing storage or administration the proposed alternative must be agreed with the Pharmacy Department. These local systems and facilities will be subject to audit.

13.2 Scope

This Policy applies to all trials falling within the scope of the EU directive regardless of licensing status, indication, funder, sponsor or source. For guidance on establishing if a trial falls under this directive there is the MHRA's algorithm entitled "is this a trial of a medicinal product?."[33] Researchers should always seek JRMO advice if there is any doubt. The JRMO will, if required, contact the MHRA helpline for a final decision on whether or not a trial falls under the scope of the EU directive.

13.2 Policy

(a) Regulatory and local approvals

In addition to ethical and local NHS approval, trials involving an investigational medicinal product (IMP) should follow current submission guidelines and the processes required to submit an application the Medicines and Healthcare products Regulatory Agency (MHRA).

A relevant Ethical Review Committee must first approve any clinical trials involving patients of BH or healthy volunteers. A Principal Investigator wishing to prescribe drugs for an investigator led trial should ensure that where appropriate the licensing authority (MHRA) has been informed. This may involve application for a Clinical Trial Authorisation (CTA). This must cover clinical trials of unlicensed products, sponsored by pharmaceutical companies. Prior to prescribing clinical trial material the Principal Investigator, or pharmaceutical company trial co-ordinator should discuss with BH's Pharmacy (the clinical trials pharmacist) the exact procedure and necessary information for prescribing the trial material. For clinical trials involving in-patients it is the Principal Investigator's responsibility to ensure that all staff involved in the study are well informed and given reasonable notice of pending clinical trials.

Local appropriate pharmacy approval must be sought and received. Only upon receipt of all appropriate approvals will BH or QMUL permit a trial to start.

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[32] The Declaration of Helsinki (1996); ICH Good Clinical Practice (1996); EU Directive 2001/20/EC & GCP Directive 2005/28/EC; The Medicines for Human Use (Clinical Trials) Regulations 2004 (and all its amendments); The Data Protection Act 1998; The Research Governance Framework for Health and Social Care 2001,Revised 2004

[33] Algorithm is at http://www.mhra.gov.uk/home/groups/l-unit1/documents/websiteresources/con009394.pdf

(b) Prescribing and Administration

All prescribers and persons administering IMP must be suitably trained and delegated to do so by the principal investigator.

All IMP should be prescribed using a pharmacy approved prescription. The prescription must be clearly labelled “For clinical trial use.”

(c) Patient Safeguards

Informed consent must be obtained as per local and national policies. The Principal Investigator is responsible for informing patients with regard to trial medication and the potential for any harmful effects. Arrangements must be in place to indemnify BH or QMUL for any claims against them relating to medicine-induced injury.

All patients and volunteers must be given study information that gives the name of the trial and a named 24-hour contact with telephone number. This may then be passed to BH’s Pharmacy in the event of a query.

(d) Supply and storage

All medication intended for clinical trial use should be delivered to the Pharmacy Department and stored under its direction. It is normally inappropriate for stock to be stored on wards, clinics or private offices. Where normal arrangements would seriously affect the running of the trial, the pharmacist may consider authorising alternative arrangements. This must be documented and an audit of the procedures and conditions must be carried out. The trial will be subject to on-going audit by the pharmacist in these circumstances. Any significant breaches of GCP, or the safe and secure handling of medicines policy, may result in suspension of the trial whilst satisfactory arrangements are put in place.

(e) Dispensing

BH’s Pharmacy should have a clear dispensing procedure for each clinical trial and must ensure correct labelling of trial material, as per clinical trial application and Sponsor instructions.

(f) Information

Pharmacy should hold within its Pharmacy Trial File information relevant to each clinical trial, including a protocol, MHRA, ethics and JRMO approval letters, an investigator’s brochure or summary of product characteristics, and randomisation codes, where appropriate.

Note: This policy applies to both BH and QMUL.

14. Use of medical devices in research

14.1 Background

Medical Devices are utilised in research in a number of ways:

- Development of a new device in-house may be the primary purpose of the project.
- Devices may be purchased or introduced on loan in order to enable research to be carried out.
- Existing devices may be altered for use in research.
- Commercial devices may be tested for safety and efficacy as a potential means of improving practice.

The purpose of this policy is to ensure that:

- Devices used for the purposes of research have undergone basic safety checks.
- Appropriate departments within BH and QMUL are aware of and have approved the use of the device.
- The risk associated with the use of experimental devices is minimised.
- Experimental devices do not pass into mainstream usage without consideration of safety, fitness for purpose, capacity for sterilisation, training needs of potential users, maintenance and cost effectiveness.
- Any incidents or near misses relating to experimental devices are reported using BH incident reporting procedure.

This policy needs to be read in conjunction with the Trust's Decontamination of Medical Devices Policy[34]. Full details of BH management of medical equipment can be found at: http://bartshealthintranet/Policies-and-Guidelines/Documents/Policies-Trust-wide/Medical-Equipment-Policy.pdf

14.2 Policy

This policy is designed to ensure that BH and QMUL meet their legal obligations concerning the use of medical devices in Clinical Research.

This policy follows BH's existing guidance in the context of devices used in research. This policy is applicable to BH and QMUL personnel using medical devices in research, regardless of type of participant or setting.

It should also be noted that any devices that are developed 'in house' and are not on the market are not covered by any MHRA regulations and therefore, it is the responsibility of BH or QMUL to ensure that their use is safe and appropriate.

14.3 General Points

- All research that intends to use human subjects must have appropriate ethical approval (See Ethics policy with in this document).
- All devices whether used to carry out the research or developed as the subject of

[34] Barts Health Decontamination of Medical Devices Policy, 4 February 2014: http://bartshealthintranet/Policies-and-Guidelines/Documents/Policies-Trust-wide/Decontamination-of-Medical-Devices.pdf

research must be registered with BH Clinical Physics / Equipment Department and JRMO.

- All equipment used in Clinical Trials of Medicinal Investigational Products (CTIMPs) must be registered with BH Clinical Physics / Equipment Department and JRMO to ensure that the equipment used is appropriately recorded and maintained.
- Researchers not involving BH patients or staff should seek advice and guidance from the JRMO and BH Clinical Physics / Equipment Department, who will on a case-by-case basis provide risk management and safety reviews.
- It is the responsibility of individual CAGs or Faculties to ensure that all equipment in use is included in an equipment inventory.
- CAGs and Faculties must also ensure that Clinical Physics are notified if equipment is re-located.
- All experimental equipment intended for clinical interventions must be clearly labelled and registered as 'Research only.'
- Medical equipment intended for research must not be used in routine clinical practice without written approval of Clinical Physics.

14.4 Purchasing Equipment for Research

All equipment purchased for use in research, either by BH or QMUL must go through the approved BH or QMUL Procurement Process. This is designed to ensure that consideration of installation, consumables, training, staffing, maintenance and disposal costs are considered before a device is purchased. The selection process should also consider any risks associated with the use of the equipment. Additional risks could be introduced by equipment diversity i.e. where users are not trained to operate the range of equipment in use. Purchasers should aim to standardise the number and range of equipment in use. Decontamination processes and cross infection risks must also be considered. Researchers should always seek advice from Clinical Physics and Clinical Risk Departments before introducing a new piece of equipment.

Where a tendering process is required, Clinical Physics should be informed and a tender specification approved. The department should also be involved in the final selection process.

Before any order is made, the Supplies Manager must ensure that a completed Pre-Purchase Questionnaire has been obtained from the Supplier and has been approved by Clinical Physics.

14.5 Equipment Loaned for Research

Although there is no prohibition on accepting loans, it is important that the arrangements are transparent and do not carry a longer-term commitment by BH or QMUL to the organisation making the loan. It is also important to understand and be clear about any expectations from the company that accompany the loan. Therefore, before entering into any agreement, researchers must consult the JRMO and Clinical Physics / Equipment Department and:

(i) Ensure there is no commitment to buy or pay rental at the end of a specific period and that the company is aware that QMUL or BH undertakes no commitment to purchase, even if the equipment proves itself in use.
(ii) Be clear about whether or not BH or QMUL must pay for wear and tear. If expected, the amount should be specified in advance
(iii) Be clear about whether QMUL or BH is expected to pay for any damage to the equipment whilst on loan and the maximum liability
(iv) Consider the cost of consumables and or maintenance etc. If revenue costs are how they will be funded must be clarified
(v) Be clear about other commitments from the loan i.e. time spent in talking/demonstrating the “product” to other potential purchasers and also the medico-

legal, confidentiality and insurance issues associated with such practice.

(vi) Consider overall value for Money.

(vii) Follow BH or QMUL Standing Orders on tendering and quotations for any purchases of consumables or associated items.

(viii) Clarify the position at the end of the loan period.

(ix) Be clear about the medico-legal position particularly on any additional risks to individuals, BH or QMUL.

(x) Discuss and secure the agreement for the loan with the relevant Clinical Director and General or Institute Manager.

(xi) Ensure the equipment is clearly labelled as “on loan & from whom” and does not become confused with BH assets. It must not be included on BH’s or QMUL asset register.

Finally, it is important to undertake a full evaluation of the equipment to assess its effectiveness and suitability. A report should be compiled for the benefit of other staff both in the directorate/institute and other directorates/institutes that might be interested.

If subsequently the decision is taken to purchase the equipment or enter into some other financial arrangement, then BH or QMUL’s business case rules apply.

14.6 Safety Testing

All new portable devices for use in BH or on BH patients or staff must be delivered to the relevant Clinical Engineering Workshop. Non-portable equipment should be delivered to the user site and Clinical Physics informed. All new equipment will be given a full functional and electrical safety test before use. This will either be carried out in house or Clinical Physics will arrange for the Supplier/Manufacturer to carry out the appropriate tests. All tests will be documented and held by Clinical Physics.

For research not using BH patients or staff, individual arrangements should be made with Clinical Physics for safety testing prior to use.

14.7 User Training

Before equipment is used the Investigator must ensure that all staff are adequately trained in its use and this training is documented. They must also ensure that user manuals and operating instructions are available locally. No member of staff should use the equipment until they are declared competent to do so. If user instructions are produced by the CAG or Faculty rather than the manufacturer, their adequacy must be checked by Clinical Physics.

14.8 Maintenance

Researchers must be clear who provides maintenance for any equipment used in research. Costs of maintenance of equipment should be sought from the funder. Maintenance will normally be carried out to manufacturer’s recommendations. Where maintenance is carried out to a lower level than specified by the manufacturer, the reasons for the change should be documented and a risk assessment carried out. All external organisations providing maintenance services must be accredited to a recognised quality assurance standard by an appropriate accreditation body. Details of all maintenance should be recorded and records kept for a minimum of 11 years after the disposal of the equipment or 20 years after the end of the research, depending on which period is longer.

14.9 Risk Management

All equipment to be used in clinical interventions must be capable of disinfection unless it is designated 'single use. No single use item may be re-used under any circumstances. Researchers are advised to seek advice from Sterile Services in this respect.

All experimental devices, i.e. new products or amended existing products, must be subject to a risk assessment by Clinical Physics.

In the event of an incident or near miss involving equipment for research, the Clinical Risk Department must be notified through the normal channels. Where the device is the subject of the research, the Ethics Committee and the JRMO should also be informed. BH and QMUL incident reporting policies should be followed.

14.10 Storage of Devices

Custodians of equipment and investigators should ensure that medical devices are stored in accordance with manufacturer's instructions. Where a device is experimental, advice on storage should be sought from the Clinical Physics Department. No experimental devices should be stored in a way that may lead staff to believe they are for routine clinical use, i.e. they should be clearly identified as being for research purposes only and be stored separately.

14.11 Disposal of Devices

Medical Equipment which is no longer in use or has been replaced should be disposed of through Clinical Physics / Equipment. It should also be removed from the equipment inventory. Any radioactive substances should be disposed of in accordance with the Radioactive Substances Act, 1993 and the Radiation Protection Officer advised.

14.12 Background for Using Devices in a Clinical Setting

The Medical Devices Directive 93/42/EEC, the In Vitro Diagnostic Medical Devices Directive 98/79/EC, and the Active Implantable Medical Devices Directive 0/385/EEC have been implemented in the United Kingdom by the Medical Devices Regulations 2002 (SI 2002 No 618). [35]

The purpose of the medical devices directives are the harmonisation of technical standards and essential safety requirements to enable medical devices to be marketed freely throughout the European Economic Area.

Medical Device means "an instrument, apparatus, appliance, material or other article, whether used alone or in combination, together with any software necessary for its proper application, which:

a) Is intended by the manufacturer to be used for human beings for the purpose of:
- Diagnosis, prevention, monitoring, treatment or alleviation of disease.
- Diagnosis, monitoring, treatment, alleviation of or compensation for an injury or handicap.
- Investigation, replacement or modification of the anatomy or of a physiological process.
- Control of conception.

b) Does not achieve its principal intended action in or on the human body by pharmacological, immunological or metabolic means."

Scope of regulations

[35] EU Directive 93/42/E of 14 June 1993 concerning medical devices In Vitro Diagnostic Medical Devices Directive 98/79/EC The Medical Devices Regulations 2002 No. 618

If a device is made by one legal entity for use on or by the patients of that same entity, there is no placing on the market and the Regulations do not apply.

When a health care establishment or other body manufactures devices with the intention of marketing them to another legal entity, as opposed to treating their own patients, MHRA would regard such manufacture as being covered by the Regulations.[36] This would include transfer between QMUL and BH. However, there are examples of medical devices being transferred between healthcare establishments where, although there is a transfer between legal entities, the product is not placed on the market.

Products manufactured in–house in a healthcare establishment and undergoing testing for proof of concept are considered medical devices. They are, therefore, subject to the provisions of the Medical Device Regulations. In circumstances where the in–house manufacture intends to commercialise the device, application must be made (irrespective of whether the manufacturer and subjects are part of the same legal entity).

If a clinical investigation is to be carried out, the investigator must ensure the Competent Authority is notified of a proposed clinical investigation. MHRA guidance notes [37] clearly sets out procedures. Advice and guidance should always be sought from the JRMO.

The full details of BH management of medical equipment can be found at: http://bartshealthintranet/Policies-and-Guidelines/Documents/Policies-Trust-wide/Medical-Equipment-Policy.pdf

BH and QMUL (through the JRMO) will review the Medical Device production and research activities to decide whether or not they are covered by the Regulations.

The JRMO in conjunction with the Clinical Physics Department will decide whether regulations apply. The following should be considered:

- Whether the product falls within the definition of "device".
- Whether the product is at such an early stage of development that the scope of its application and therefore its intended purpose has yet to be precisely defined.
- Whether the body making or developing the device falls within the definition of "manufacturer" in relation to that particular product.
- Whether the device is being "placed on the market".

For any activity that is identified as subject to the provisions of the Regulations, all relevant obligations must be identified and complied with. Even if it is decided that the activities in question are not subject to the Regulations on medical devices, there are Institutional responsibilities under the general law (including consumer protection legislation) and a responsibility to ensure the safety of patients, users and any relevant third party.

Note: This policy applies to both BH and QMUL.

[36] The Medical Devices Regulations: Implications on Healthcare and other Related Establishments, Bulletin No. 18 Competent Authority (UK), February 2011

[37] MHRA-EC Medical Devices Directives Guidance Note 1 (Guidance for Manufacturers in Clinical Investigations to be Carried out in the UK, February 2012)

15. Indemnity

15.1 Background

Clinical Trials and other research studies undertaken by employees of BH, QMUL and external Researchers, carry an element of risk for research subjects, (who may be BH Patients or volunteers entering QMUL projects), researchers, research sponsors and employing organisations. The principal objective of the Joint Clinical Trial Compensation Policy (12 above) is to ensure that where subjects suffer harm as a result of participation in a study, they will be compensated – if, of course, the circumstances under which the subject was harmed, meets the criteria set out in the policy. The objective of this policy is to set out the indemnities that are required to be in place in order for the Compensation Policy to come into force.

15.2 Policy

(a) Commercially Funded Trials

All organisations in the UK are required to ensure that before any trial funded by a commercial concern, pharmaceutical company or Devices Company commences, a properly authorised and signed Form of Indemnity for Clinical Studies is completed by the JRMO, and submitted with the Research Ethics Application. This Form will be in the prescribed Association of the British Pharmaceutical Industry (ABPI) format. This legally binding agreement provides indemnity for both trial subjects, and BH or QMUL, ensuring that if harm is caused by the product under investigation, or because of deficiencies in the trial protocol, the subject will be compensated (see Policy 12 above) and BH or QMUL indemnified from liability to pay the claim. Contracts will usually follow the appropriate standard model.

(b) Non-commercially Sponsored Trials

In general, where a trial is sponsored by a non-commercial organisation, the funder that might be Research Council, Government Organisation, Charity or NHS Trust, shall remain responsible for the design of the study and any materials, drugs or equipment supplied, if they have written the protocol and are providing the drugs or devices. Where a collaborative study is entered into, individual employing organisations are responsible for the acts of their employees whilst on related business. Responsibility for protocol and product liability will vary according to the nature of the trial and the acceptance of responsibility by the funder. Thus indemnity may be provided by:

- A commercial company that is lending support to a non-commercial study by contributing free drugs, with or without additional financial support, that might be unlicensed for a condition or indication that is the subject of the research study being undertaken and for which the company is not providing indemnity. The company will be expected to provide a guarantee that the products supplied are the subject of a manufacturers' warranty.
- A funding organisation, such as the MRC, on strictly limited Terms and Conditions that are not in the ABPI prescribed format.
- QMUL or BH that in the absence of an agreement with a funder takes responsibility for meeting product liability claims.
- Where an unlicensed product is used beyond the trial period, on a named patient basis, or for humanitarian purposes, responsibility is wholly that of the treating doctor. Doctors are required to maintain adequate and appropriate professional Indemnity Insurance and notify their protection society and the appropriate regulatory body if they intend to use unlicensed products.

15.3 Negligence

Organisations are required to indemnify research subjects and funding organisations from claims arising from the negligent acts of their employees. Where an ethics application is required and before submission to the NHS or QMUL Ethics Committee, investigators are required to submit the Ethics Application Form and Protocol/Project Specification to the JRMO for review. The Office will issue a Provisional Letter of Sponsorship, which includes terms under which indemnity would be issued. Once Ethics Approval has been given for a study, the Office will issue a Final Letter of Sponsorship, which incorporates confirmation of Indemnity. Where QMUL is the legal sponsor this Indemnity covers QMUL or BH staff, patients and partner organisations inclusive of TMSC's and third party organisation up to the limit of liability.

Where BH is the legal sponsor their indemnity is covered through the NHS Litigation Authority and only covers BH staff and patients. Where Investigators from other organisations are conducting a study on QMUL or BH premises, a letter of Indemnity from the sponsoring organisation must be submitted to the JRMO and Ethics Committee. Investigators must continue to inform the Office and Ethics Committee(s) of changes to the Protocol/Project Specification in order that Indemnity cover is maintained. Failure to inform the Office and/or the Ethics Committee(s) of the intention to conduct a study will be viewed as a breach of an Investigator's contract of employment and investigators could have personal liability for any harm resulting to a patient or claims made by a funder (see Policy 12 above).

15.4 Health and Safety

Staff involved in Research and Development activities are bound by all published Health and Safety Regulations, as set out in QMUL or BH Policies on Health and Safety at work.

15.5 Insurance

QMUL secures insurance for its research liabilities from a commercial insurance company. Whilst most of its liabilities are covered, exclusions within the policy may require additional insurance cover to be purchased. The JRMO must bring to the attention of QMUL's Purchasing Officer any instances where additional cover needs to be purchased from an external insurer.

BH insures its liabilities through the NHS Litigation Authority's liabilities to third parties scheme.

Note: This policy applies to both BH and QMUL.

Section E: Financial probity in research

16. Identification and protection of Intellectual Property

16.1 Background

Both QMUL and BH undertake research in order to make progress in our understanding of the world and wish to ensure that any discoveries are developed to bring a benefit to society and the world. In order to ensure this can happen both organisations recognise the need to protect their intellectual property.

16.2 BH Policy

16.2.1 Background

Intellectual Property can be defined as inventions, designs, project results, prototypes, systems, processes, formulae, publications, internal reports, natural discoveries, ideas, knowledge or know-how derived or developed as part of an employee's work for BH.

BH is obliged to protect and where possible exploit to the advantage of the NHS generally, and in particular for the financial benefit of BH, the product of its research activities. The following Intellectual Property Policy is geared towards protecting the interests of BH and its staff with regard to their Intellectual Property Rights.

It is incumbent to exploit, whenever possible, the product of its research activity, if that product has potential commercial value or could lead to a new service development. Should a commercialisation route be defined then the income streams that could arise from the successful exploitation of BH's Intellectual Property (IP) will provide a valuable contribution to BH's infrastructure costs and an attractive source of unencumbered research funding.

The principal methods of exploitation are as follows:

- Outright sale of IP to commercial organisations.
- Licensing Agreements: where companies are licensed to utilise BH's IP in exchange for a royalty based on the value of sales the company makes.
- Sale of IP rights in exchange for specific initiatives e.g. funded posts, purchases of capital equipment, etc.
- Through joint ventures with other non-commercial organisations, e.g. medical charities, local authorities, etc.
- The creation of spin-out companies

16.2.2 Ownership

Unless otherwise explicitly agreed, all Intellectual Property (IP) developed by individuals whose primary employment is with BH will be vested in BH.

Where the principal employer of an individual who holds an honorary contract with another organisation is BH, then the ownership of any IP arising from their work is vested in BH.

Should an employee have a joint appointment with another organisation then the ownership of any IP developed by the individual will be joint between the employing organisations. The determination of ownership in these circumstances will be on a "case by case" basis and will be subject to a written agreement between the parties with due regard to the financial investment of each organisation in the development of each item of IP.

Should BH decide not to prosecute a particular piece of IP ownership rights will be assigned to employees, who will be free to take whatever action deemed necessary at their own expense to protect and exploit the IP without further involvement of BH.

16.2. 3 Contracts

A contract is usually the major mechanism for protecting BH's IP. All contracts and agreements for research projects taking place on BH premises and utilising BH resources must be reviewed by the JRMO and signed by an authorised BH Officer. Failure to inform the JRMO may make individuals liable under BH's Policy on Misconduct in Research (see policy number 23).

The JRMO must review all contracts and agreements to ensure appropriate protection and exploitation of IP and clarification of ownership.

Ownership of both background IP (IP that BH employees bring to a project) and foreground IP (IP generated during the course of a project) must be formalised.

Where ownership of the IP does not vest in BH, contracts should clearly set out the distribution of income, received from the exploitation, to the various parties, according to the level of their individual contributions to the development of the IP.

16.2.4 Duty to keep records

Although it is difficult to establish when, from a concept or idea, a clearly definable piece of intellectual property emerges, it is vital that during the course of a research project the results are clearly recorded.

Employees, who are investigators and their fellow or subordinate researchers, as the research progresses, will keep laboratory notes to a standard format.

Once research into a concept or idea results in definable conclusions the outcome will be clearly recorded through an appropriately structured report.

Where an outcome has a potential commercial value, the report will be sent to the JRMO or a specifically designated individual.

The potential commercial value of the IP will be assessed by BH and, if necessary, action taken to protect the IP and initiate the exploitation process.

16.2.5 IP Protection

BH has a duty to adequately protect its IP. Ensuring that effective protection is maintained can only be guaranteed with the co-operation of BH's researchers.

All BH employees will keep confidential, unpublished information pertaining to the research they or their colleagues are undertaking.

Before discussions can begin with potential external research sponsors, a confidentiality undertaking will be concluded between BH and the external organisation and signed on behalf of BH by an authorised officer and the employee.

All visitors to BH's work sites whom are not employees of BH will sign a confidentiality agreement before they obtain access to sensitive research areas.

Copyright is automatic and applies to books, computer programmes, publications, lecture notes, reports, laboratory notes, etc. Adding a note at the end of the text to the effect that copyrights belongs to BH NHS Trust will protect all such texts.

A copy of all copyright texts will be sent to the JRMO, which will maintain a central register of all of BH's copyright material.

Where, in the view of BH, a piece of IP requires patent protection, BH's patent agents will be approached to draft a specification and submit an application to the Patent Office. Such action will be taken only if a clear commercialisation route can be identified and forecast income streams exceed the costs of patenting.

16.2.6 Publication

BH understands the importance of disseminating the results of its R&D activities, for the public health benefit and to further its research strategy. However, it is important that any IP contained in published material has been adequately protected to ensure that BH's ability to successfully exploit any potentially valuable IP is not compromised.

Staff will, therefore, be encouraged to consult the JRMO before articles are submitted for publication or information disclosed to a third party.

Should protection be required the JRMO will take steps to ensure that such protection is put in place before publication of the research findings.

The JRMO will ensure that any delays in publication required in respect of this policy will be minimal and in no circumstances shall such delays exceed 6 months from the date of receipt of the article.

16.2.7 Exploitation

BH will establish the mechanisms required to identify its IP and its commercial potential. 'NHS bodies should minimise the risk that they take on by assigning or licensing any IP to commercial or other organisations able and willing to meet all or most of the costs of exploitation' (Research Governance Framework, 2001). The JRMO will take overall responsibility for ensuring that BH's IP is made available to potential industrial partners, providing services through a contracted IP portfolio management company or through an in-house provision.

Staff involved in Research & Development activity in BH are required to bring to the attention of the Director of Academic Health Sciences any item of IP developed in the course of their employment.

The decision to pursue a commercial development will rest with the Director of Academic Health Sciences. The resources that NHS bodies devote should be commensurate with the likely benefits and with other calls on their funds.

BH recognises that staff involvement with the development of its IP should be rewarded through a share in the proceeds of any successful exploitation. Income received by BH will be distributed in the following manner:

Net Total Cumulative Income	Inventor's Share %	BH Share %
0-£5,000	100	0
£5,000-£45,000	75	25
£45,000-£100,000	50	50
£100,000 +	33.3	66.7

In dealing with BH exploitable intellectual property, the JRMO will bring to the notice of inventors and all those involved in the commercialisation process, BH's policy on Standards of Business Conduct. The internal regulations in this policy will be strictly followed, particularly with regard to potential conflicts of interest.

16.3 QMUL policy

16.3.1 Introduction

QMUL affirms the inherent value to its mission of research and its applications, and their core role in our primary commitment to the public good.

QMUL will foster the free and open creation and dissemination of Intellectual Property or Know-how (IP) and its best use; this will include a clear framework providing for the allocation of time and resources to the authors or creators of IP, and generous terms for the allocation of the financial benefits of the commercialisation of that IP to those authors or creators.

This policy is based upon the following principles:

- That IP produced at QMUL should be used in the public interest in general, whilst recognising that it may be appropriate for QMUL and/or inventors or authors to gain financial benefit from its commercialisation, with those benefits being defined so as to encourage those inventors or authors to commercialise that IP;
- That it is required to protect the traditional rights of scholars concerning their work, and to encourage the free and open creation and dissemination of works produced by researchers and scholars;
- That any significant financial or other resource support by QMUL for the development of any IP should be identified, and that recognition should be made of QMUL's responsibility as a charity and recipient of government and charity funding to realise appropriately and proportionally any gains from that development, for the benefit of its future staff and students; in making use of significant QMUL resources for the development of any IP, a QMUL employee is accepting the terms of this policy;
- That the work done by academic staff in the creation and/or commercialisation of IP covered by this policy should be recognized in staff appraisals and assessments of workload and promotion.

The full QMUL Policy on Intellectual Property comprises this summary document as an overarching guide, together with any approved subsidiary documents covering particular areas in more detail.

16.3.2 Inventions

"Inventions" are any research outputs that can be reasonably identified as having commercial potential including patentable or potentially patentable discoveries or ideas and any associated technology required for their development or application.

All rights in Inventions created by a QMUL employee in the course of their employment, or otherwise but with significant use of QMUL resources, will generally belong to QMUL.

If an employee or employees of QMUL create an Invention outside the course of their normal employment duties, without significant use of QMUL resources, then that Invention will belong to the employee or employees, jointly if not otherwise agreed.

Ownership of Inventions created by an employee or employees of QMUL with an external body will be determined by a QMUL-approved agreement; where this has not been defined in advance, ownership will in the first instance belong to QMUL.

16.3.3 Academic works

"Academic Works" are those writings, research outputs other than Inventions, and other productions (for example video or audio recordings) that are aimed at communicating the progress or results of research or scholarship. The IP rights to the Academic Works created by individuals whilst QMUL employees, and the rights to any revenues derived from these, remain with their authors, however QMUL has a licence to use those works and a right to sub-licence their use, in order to advance its higher educational mission ("Academic Purposes"). This is a condition of QMUL waiving its rights of ownership of the relevant IP.

Where QMUL involvement in the creation of an Academic Work consists of significant investment of additional funding or resources not in the normal course of employment, then ownership and rights to any share of royalties or income shall be fairly apportioned between QMUL and the author/s.

Where Academic Works are created subject to an agreement between QMUL and a third party then any copyright issues will be handled according to the terms of such an agreement.

16.3.4 Teaching and administrative materials

"Teaching Materials" and "Administrative Materials" are any materials produced by QMUL employees in the course of teaching and administrative work, respectively, undertaken in the course of their employment.

QMUL agrees and acknowledges that all performers' rights in any Teaching Materials, including any video or other recording of a QMUL employee's lectures or presentations, or similar works which are performances in IP terms, are owned by the employee. Each employee grants QMUL rights to use such materials, and their recordings, for Academic Purposes.

QMUL owns the IP rights to Teaching Materials and Administrative Materials, whilst granting use of those materials by their creator for any purposes consonant with their QMUL employment.

With regard to Teaching Materials produced whilst they were in QMUL employment, QMUL grants any former employee the personal licence to unrestricted non-commercial use of that material elsewhere. This includes use of that material as the basis for creating new teaching materials for another academic institution.

If QMUL decides to commercialise Teaching Materials outside its Academic Purposes, then those QMUL employees involved in their creation will have a fair and reasonable share of the proceeds of commercialisation.

A current or former QMUL employee may object to the use by QMUL of Teaching or Administrative Materials in cases where they are identifiable as a creator, if the use of that material is felt to be to their detriment or misrepresents the creator. The QMUL IP Committee will rule on such objections.

If a current or future employee wishes to commercialise Teaching Materials, the agreement of QMUL is required, but will not unreasonably be refused. The terms of such agreement, which might include a share by QMUL in the proceeds of commercialisation, should be negotiated with Queen Mary Innovation (QMI).

16.3.5 Performances

IP ownership of recordings of creative performances, such as dramatic or musical performances, remains with the performer/s. For performances created by QMUL employees in the course of their employment, QMUL has automatic permission to use those works for Academic Purposes. For joint performances involving third parties, IP ownership will be according to prior agreements among those parties.

16.3.6 Software and Databases

QMUL recognises the value of open source software and open data, and the related licensing arrangements, for promoting knowledge creation and dissemination.

Software or databases that are created as part of the process of communicating the progress or results of research or scholarship, and that do not have reasonably foreseeable commercial potential, are to be treated as Academic Works under this policy.

Any software or databases created by QMUL employees in the course of their employment that may reasonably be foreseen at any given time to have commercial potential shall be treated as Inventions from that point under this policy. Any cases of doubt should be referred to the QMUL IP Committee for a ruling.

16.3.7 Student creations

The IP rights to works created by QMUL students, including Inventions, are in general owned by the creator/s, with QMUL having permission to use them for Academic Purposes. If student works are created in connection with an agreement with an external body IP ownership will be determined by that agreement. If the works are created whilst the student is in employment using QMUL funds, or whilst using significant QMUL resources, then QMUL owns the IP rights. This includes cases where the student work is largely designed and led by a QMUL academic or academics, which could include research or other project work.

Notwithstanding the above, QMUL may from time to time provide financial and other resources through entrepreneurship schemes, competitions and initiatives with which its students can engage. QMUL may, at its discretion, choose to agree joint ownership or to waive its claim to any IP generated through such activities in favour of the students. Any such agreements will be set out in the relevant terms of the internal scheme, competition or initiative.

16.3.8 Other staff and associates

The rights to all IP created by non-academic staff (staff without teaching or research as a major component of their contract), in the course of their employment or with significant use of QMUL resources, are owned by QMUL.

Unless agreed otherwise in any contract between QMUL and a third party, Academic Works and Inventions arising from the non-clinical work of clinical academics on QMUL contracts shall be treated in the same way as those arising from the work of academic staff. Those arising from the clinical work shall be treated under the terms of the contractual agreement with the appropriate health authorities; where these are not described the QMUL policies shall apply.

Academics or researchers who are affiliated with but not employed by QMUL (“Associates”) are generally required to transfer to QMUL any IP they create using QMUL resources in the course of their affiliation. Such Associates will be treated as if they were QMUL employees for the purposes of sharing revenue.

16.3.9 Disclosure

QMUL employees are required to disclose in a timely fashion all Inventions or other works of foreseeable commercial value that have been created in the course of their normal duties of employment with QMUL, or during joint work with an external body, or where significant use of QMUL resources has been made. Student Inventions where the IP is owned by QMUL under Section 7 should also be disclosed. All such disclosures should be made to QMI.

Information relating to Inventions or other works that could reasonably be foreseen to have commercialisation opportunities should be treated by QMUL staff and students sensitively and disclosed only to relevant QMUL employees prior to protection by a suitable agreement.

Each School or Institute of QMUL should have a policy for encouraging innovation and achieving impact for its research and scholarship; this policy should cover the operation of a system that identifies any non-commercial use for the purposes of impact, and discloses to QMI any works by members of their staff or (where relevant under Section 7) student body that have the potential for commercial use.

16.3.10 Commercialisation

QMUL's policies on the commercialisation of Inventions created by Inventors also apply in general to other works with commercial value created by authors, subject to any specific statements made within the IP Policy.

QMI, acting on behalf of QMUL, is responsible for the identification, evaluation, protection and commercialisation of Inventions owned by QMUL. Whilst this may not necessarily involve purely maximising financial return in general, QMI will work with the Inventors to identify appropriate third parties to commercialise the Inventions or works under the best terms.

QMI will agree with the Inventor(s) a strategy for the development, protection and commercialisation of an Invention. This will include an agreement with the Inventor's line managers covering the appropriate recognition of, and allowance for the time and other resources required for such activities.

Neither QMUL nor QMI will promote or commercialise any Invention that would clearly conflict with any ethical policies agreed by QMUL, nor with the ethical principles of the Inventor/s.

QMUL recognises that commercialisation of IP may not always be appropriate and that on occasion it is in the best interests of knowledge transfer or exchange to place IP in the public domain.

If QMI decides not, or is unable, to commercialise the Invention within a reasonable timeframe then the Inventor(s) may ask for it to be assigned to them. Such assignment will include a licence back for use by QMUL.

QMUL shall be solely entitled to use its name, trademark, service mark, corporate name, domain name or any other mark in respect of commercialization of any product or service.

16.3.11 Benefits

QMUL owns the revenues received from Commercialisation of its Inventions or other works, however in the spirit of the principles in Section 1, the following sharing arrangements shall apply. Where more than one author or inventor has played a significant role in the creation of an Invention and there is no prior agreement amongst them on the sharing of benefits then the Inventor benefits shall be shared equally between the Inventors. The sharing of Net

Revenue from any works not covered by sections A and B below shall be consistent with the arrangements described, and in line with the principle that the inventors or authors will have a fair and reasonable share of the proceeds of commercialisation.

A. Sharing of Revenue from Licence/Sale of Inventions

The income to be shared between QMUL and the Inventor(s) is defined as the cumulative Net Revenue from the licensing of Inventions, or from the total amount of the sale, to a third party. The following shall be deducted in calculating the Net Revenue: VAT, any patent protection or legal costs, any revenue sharing costs, employer tax liabilities, and any other expenses directly related to obtaining or commercialising the Invention (excluding QMI staff resource costs or any QMUL funds contributed to develop the Invention).

In the following, "Significant Internal Funds" means a total sum in the region of £50,000 from QMUL funding streams and/or patent and other legal expenditure, and "Significant QMI Resources" means an agreement reached with QMI on the strategy, means and likely timescales for commercialisation, and the reasonable efforts, normally within a one to two year period, by QMI to deliver on this including, but not limited to, seeking translational development funding, leading on new spinout investment, or marketing and negotiating licenses with third parties.

Where an Inventor or Inventors makes no use of Significant Internal Funds or Significant QMI Resources then they will have 90% of Net Revenue. Where use is made of either Significant Internal Funds or of Significant QMI Resources, then the Inventor/s will have 70% of Net Revenue. Where both such Funds and Resources are used then the Inventor/s will have 50%. The percentages or amounts under conditions where significantly greater or subsequent funds or resources are to be utilised will be determined by prior agreement between QMI and the Inventor/s.

The QMUL share of Net Revenue will be apportioned between QMUL and the Resource Centre. The latter will be held at Faculty level and normally allocated to the School or Institute of the inventor(s), with a significant proportion of that allocation going to the research area of the inventor(s). Where the QMUL share of the Net Revenue upon sale, or cumulative license income, is less than £1,000,000, then the Resource Centre will be allocated the entire QMUL share. The distribution of any QMUL share that is in excess of these amounts will be decided by the QMUL Senior Executive.

B. Sharing of revenue arising from the formation of a new spinout company

Where any Invention is commercialised through the creation of a new spinout company, the academic founder benefits will be represented by shares in the spinout company.

For clarification QMUL benefits are those realised from the sale of shares in the new spinout that were granted to QMUL (not including the shares provided to the academic Founders).

Where an Inventor or Inventors makes no use of Significant Internal Funds or Significant QMI Resources then they will have 90% of the QMUL shares. Where use is made of either then the Inventor/s will have 70% of the QMUL shares. Where both such Funds and Resources are used then the Inventor/s will have 50%. Percentages or amounts under conditions where significantly greater or subsequent internal funds or resources are to be utilised will be determined by prior agreement between QMI and the Inventor/s.

The QMUL share of any proceeds from the sale of the QMUL shares will be apportioned between QMUL and the Resource Centre (as defined in 11.4). Where the realised value of the QMUL shares is less than £1,000,000, then the Resource Centre will be allocated the entire amount. The distribution of the realised value of QMUL shares that is in excess of this amount will be decided by the QMUL Senior Executive.

16.3.12QMUL IP Committee

QMUL Senate will approve a QMUL IP Committee, which will have responsibility for the interpretation of this Policy and any subsidiary policies, and ruling on any questions or disputes arising in relation to it. Senate will also approve a process for appealing against decisions of the IP Committee.

The QMUL IP Committee may review the policy from time to time and make recommendations for changes. No such revision which materially changes the QMUL IP policy will apply retrospectively from the date of its adoption. The Committee may issue guidance on the meaning and interpretation of the policy.

Authorisation

This policy was approved by the Queen Mary Senate on 9 October 2014.

Contact for questions about this policy

Please contact Queen Mary Innovation (QMI) at
http://www.qminnovation.co.uk/index.html

Note: This policy applies to BH and QMUL as indicated.

18. Costing research

18.1 Background

The guiding principles in the Higher Education Sector and NHS (through the Research Governance Framework[38]) is that through accountability and transparency all research undertaken in the public sector must be seen to offer the taxpayer value for money. Therefore, all research, whether funded through BH or QMUL using internal resources, or externally funded (e.g. Research Council, DH, charity, industry), must be fully costed.

The costing of research projects is a multi-disciplinary task. It will normally be led by the Joint Research Management Office (JRMO)'s Costing and Contracting Team, working in conjunction with the principal investigator, relevant BH and QMUL service departments (e.g. Clinical Pathology, Pharmacy, Imaging, Animal House etc), BH and QMUL Finance Departments.

The JRMO's post-award team will then manage the research project's finances to closure.

Both BH and QMUL will undertake to establish the Full Economic Cost (FEC) of all projects, regardless of its source of funding, including all direct costs and an apportionment of corporate and other relevant support services, estates and indirect costs. The JRMO will apply national costing values where these have been agreed with specific funding bodies.

18.2 Policy

The final study protocol or project specification and supporting documentation must be provided to the JRMO by the principal investigator (PI) or a nominee. At this point the PI must declare any conflicts of interest that might affect the process of establishing a full and fair economic cost for the activity.

The JRMO will review the protocol and liaise with the principal investigator, service departments and collaborating institutions, as appropriate, to calculate the direct and indirect costs of the project.

The JRMO will define and document the full cost for the project, ensuring that in all cases the costs of their respective organisations are fully assessed and included in the final FEC costing.

The full cost of the project and its method of calculation must be treated as confidential. The costing of such projects must, in all cases, including expressions of interest, outline applications or first stage applications, be undertaken by the JRMO and the methods used to determine full cost can only be relayed to funders with the agreement of the office.

Note: This policy applies to both BH and QMUL.

[38] Research Governance Framework for Health and Social Care, DH, March 2004.

19. Externally supported R&D pricing

19.1 Background

Pricing issues can be complex and each project must be considered individually. Project costing should be drawn up by the lead investigator and JRMO to establish a base on which price negotiations can take place. A minimum of 5 days should be allowed prior to submission deadlines for the JRMO to complete a detailed costing in line with funder requirements.

19.2 Policy

BH and QMUL will price externally funded projects in accordance with HEFCE and NHS pricing policies and the accepted guidelines of each external funding body. BH will use the National Agreed costing template for commercial studies. QMUL will price commercial studies at full FEC. Non-commercial projects will be costed according to the funder's conditions and nationally agreed pricing policies. In general the principles relating to Full Economic Costing (FEC) will be adhered to by both organisations. All research funds will be managed by the JRMO.

19.3 Non Commercial

For the avoidance of doubt, non-commercial research will include external funding that is for research or educational purposes. Such research is not subject to any agreement allowing a commercial or for-profit entity to impose intellectual property rights restrictions on the published results, in particular by limiting further analysis or use of such results or by delaying the availability of data and results for more than six months. Collaborative Research with a commercial entity may be considered non-commercial where the protocol predefining the research project is developed by both parties in collaboration. The subsidised price to be charged will be directly dependent on the resource requirements of the protocol and the allowable cost rules of the funding body.

19.4 Commercial

Where a commercial entity commissions research and the Trust undertakes to carry out the work according to pre-determined processes set out in the company's protocol and where the primary principles associated with non-commercial funding of research programmes do not apply, the research is classified as being commercial. The principal commercial beneficiary of the results of this type of study will be the funder of the research. Each project must be properly governed by the principles outlined in the externally supported R&D section of this document and based on FEC and a separate account should be kept for each research project through which funds should be channelled.

Note: This policy applies to both BH and QMUL.

20. Distribution of research project funds

20.1 Background

Although both BH and QMUL operate identical systems for managing external research grant accounts, their policies governing the internal distribution of research project funds, particularly overheads, differ marginally.

This policy sets out the parameters on which the process of distributing funds from external funders of research will operate in both QMUL and BH. It should be read in conjunction with, as appropriate the Trust's Standing Financial Instructions[39] and QMUL's Financial Regulation and Procedure Policies[40]

20.2 Definitions

20.2.1 Direct Project Costs: Are project funds that will be paid directly from research project accounts and will include, for example:

- **Direct staff costs:** The costs of staff directly employed to undertake a research project, where the cost is charged directly to a specific research account. Examples will be research assistants, research fellows, and research nurses etc. who are employed on a grant code for the duration of the project. Proportional staff costs are also included in this category, for example, where a proportion of the cost of a principal investigator's salary or those of other colleagues in BH or QMUL are included in a project budget.
- **Other direct costs:** Include all non-staff costs, including consumables, equipment, travel, sub-contracted services, disposables etc. These costs are also charged directly to project accounts.
- **Direct service support costs:** Include the costs of services provided by other internal departments that are directly attributable to the research. Items will include, but are not limited to, hospital service costs such as pharmacy, radiology, pathology tests and archiving. Costs may also include co-investigator's departmental costs, where the principal investigator and co-investigator are from different departments.

20.2.1 Indirect project costs: Are institutional costs that are not directly related to a research project, but are attributed in part to a project. Examples include institutional overheads, proportionally attributed service costs and capital charges.

20.2.3 Distributions: Involve the movement of funds from project accounts to a range of institutional budgets, for example transfers to QMUL/BH central or departmental staff or overhead accounts, service department accounts etc.

20.3 Distribution Policy

20.3.1 In the main, direct project costs will be charged to specific project accounts.

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[39] Barts Health Policy, 'Standing orders, reservation and delegation of powers and Standing Finacial Instructions, 29 July 2015: http://bartshealthintranet/Policies-and-Guidelines/Documents/Policies-Trust-wide/Standing-Orders-and-Standing-Financial-Instructions.pdf

[40] QMUL's Financial regulation and procedure policies can be found at: http://www.arcs.qmul.ac.uk/policy/index.html

- **Direct staff costs**: Where a new member of staff is employed on a research project, the staff member's costs will be directly charged to the research account. Where a currently employed member of staff is to be paid in full from project funds, the employee's staff costs will be charged directly to the project code for the duration of the project.
- **Proportionate staff costs:** Where a proportion of a salaried staff member's costs are attributed to a project, the sums involved will be transferred from the project account to the individual's departmental salary account code on a periodic basis. The period will be determined on a project by project basis, but will not be longer than three months.
- **Variable service support costs:** Will be transferred from the research account to the relevant service department account on a periodic basis, according to the actual value of the services provided to the project in each period.

20.3.2 Indirect Project Costs:

- **Institutional overheads - BH:** Overheads obtained from commercial clinical trials, where the full cost of the research is recovered from funders, will be distributed in the following proportions:
    - 50% JRMO account;
    - 40% to CAG Research Development account; and
    - 10% to Investigator account.

  Overheads recovered from all other sources will be transferred to centrally managed accounts. The Trust will manage this resource and may provide funds to support bridging finance for staff appointments or other contingent requirements.

- **QMUL transfers:** All overhead transfers from QMUL research accounts will be as follows:

  Research overhead distribution QMUL:

Overheads	**Institute/ Faculty/Dept**	**Central Overheads**
For FEC Projects SMD	60%	40%*
For FEC Projects Non-Med	100%	0%
Non - FEC projects	100%	0%
Note: Institutes or departments may agree individual distribution arrangements with their Respective Faculty/ School management.		

- **Proportionate service costs:** Where a proportionate charge for services is determined (as opposed to a variable cost), costs will be transferred from the project account to a specified service department account on a periodic basis. The period will be determined on a project by project basis, but will not be longer than three months.

- **Capital charges and other indirect costs:** will be transferred to the relevant BH Code on a periodic basis. Periods will not be more than three months.

20.4 End of Financial Year

It is important that all expenditure relating to services provided to a research project within a financial year are charged to that financial year and not brought forward or deferred to

another. In this respect, all funds for services provided to research accounts, salary contributions etc. must be transferred from individual research accounts to departmental accounts before annual accounts closure dates.

Note: This policy applies to <u>both</u> BH and QMUL

21. Agreements with external organisations

21.1 Background

Agreements with external organisations can take several different forms including but not limited to:

- **Collaborative or Contract Research Agreements** in which the work plan is clearly described and agreed in advance in a project protocol with a predefined deliverable. Such agreements are made with the DH, Research Councils, Charities and Industry.
- **Sponsored Post and Programme Agreements** in which research into an area of mutual interest to BH or QMUL and the external organisation is to be financed by the external organisation. Such agreements are not bound by a protocol or specify a predefined deliverable and the external organisation could be a company.
- **Site Agreements** in which QMUL or BH agrees for a local site to participate in a clinical trial for which the chief investigator is an employee of either organisation. This agreement outlines the delegation of sponsor responsibilities, as stated in the NHS research Governance Framework 2001, between two or more organisations.
- Consultancy Agreements, Material Transfer Agreements, Confidentiality Agreements, Supplier Agreements, Studentships and Sub-Contracts.

21.2 Policy

All significant external collaborations must be covered by an appropriate agreement. The final responsibility for the wording of agreements will be the responsibility of the JRMO and ultimately the Director of Academic Health Sciences for BH and QMUL's Chief Operating Officer.

The Director of Academic Health Sciences is to be BH's legal signatory for such agreements. QMUL's Chief Operating Officer is its Legal Signatory. The Research Services Director, Research Development Director and Operations Manager Pre-Award will act upon delegated powers from the two organisation's legal signatories and be an approved signatory within financial limits determined by the two organisations.

Agreements with external organisations must ensure at a minimum:

- Appropriate costs to BH and QMUL (including VAT, if appropriate) are properly recovered
- QMUL and BH's intellectual property rights are properly protected
- All risks (e.g. liabilities) are properly considered and minimised
- Time scales and contract milestones are clearly defined
- There is a clear definition of quality
- Any external regulatory, ethical and financial approvals are obtained
- There are clear statements outlining the responsibilities of the different parties involved in the agreement
- There is agreement to fulfil the obligations of confidentiality for personal information

Whenever possible, model agreements (usually NHS or Brunswick model templates) and standard wording will be used.

Where the External Organisation is unable to accept the standard contract wording, each variation will be negotiated on its merits by the JRMO. An external organisation's standard agreement cannot be accepted without a full review by the JRMO, to ensure compatibility with standard models.

Careful consideration will be given to the use of an External Organisation's standard agreement and unacceptable clauses will be modified or removed.

Should an acceptable compromise to contract wording not be possible in the best interests of BH or QMUL the Agreement with the External Organisation will not be signed.

Both BH and QMUL reserve the right to refuse funding from external organisations on ethical or moral grounds. The JRMO will liaise with BH and QMUL Officers to ensure that no contract negotiations are entered into with external funders that, in the opinion of either organisation, do not satisfy the criteria set out in their respective policies in this area or their published standards of business conduct.

Any internal dispute over the terms of an agreement, or its classification as commercial or non-commercial, will be referred to an appropriately qualified senior officer in BH or QMUL. Where agreement cannot be reached with an external funder over the content of a contract (including price) the matter will be referred to an appropriately qualified senior officer, in QMUL or BH, for a final decision.

Note: This policy applies to both BH and QMUL.

Section F: Human resource issues in research

22 Access to work at BH: Honorary Research Contracts and Letters of Access

22.1 Introduction

This policy covers individuals, who wish to work with BH employees on research projects or research collaborations, at any of its hospital sites.

Individuals who are not directly employed by BH but who work on BH premises or with BH patients or employees, or who wish to access our patient records or facilities must ensure that before they undertake any research activities appropriate access arrangements are in place.

Access approvals can take a number of forms and depend on the type of activity that individuals wish to engage in. Examples include:

- Honorary Contracts (Clinical or Research).
- Letters of Access.
- Escorted Site Visitor permissions.

The appropriateness of the access arrangement will depend in each case on what the person is intending to do whilst on site or what data they need to access in order to undertake their research. This is in accordance with the NHS Research Passport Good Practice Guidance[41] to which BH signed up in May 2010 and reaffirmed at the time of the Trust merger in 2012.

Generally speaking the following outcomes are likely:

a) The research activity is closely linked to clinical work being undertaken by the person: An Honorary Clinical Contract (HRC) issued by BH HR is appropriate.

b) The research activity involves contact with patients and will have an impact on the clinical care of the patients involved in that research: An HRC issued by the JRMO is appropriate.

c) The research activity involves contact with patients and/ or identifiable patient data, but it will have no impact on the clinical care of the patients involved in that research: A Letter of Access (LoA) issued by the JRMO is appropriate.

d) The research activity involves no access to patient or identifiable patient data (e.g. research being undertaken only involves access to anonymised healthcare records, interviews with staff or attendance at staff meetings): The appropriate access level for the researcher is as a Site Visitor. Visitor access should be arranged with the person being visited and will follow whatever is normal practice for that site.

Researchers must have in place appropriate access arrangements when visiting or working at BH. There is a mutual advantage in these arrangements as the access authority is a legal arrangement where the NHS body authorises researchers to undertake a range of activities within its organisation enabling university and other non- NHS employees to benefit from NHS indemnities, to the same extent as its own employees.. The NHS organisation must discharge its duty of care, for which the Chief Executive is personally accountable. By issuing university and other non-NHS staff with HRCs and/or LoAs, BH ensures that all researchers working on its premises or otherwise with its staff, patients, their organs, tissue or data are

[41] http://www.nihr.ac.uk/systems/Pages/systems_research_passports.aspx

contractually bound to take proper account of the NHS duty of care. Thus, appropriate access arrangements afford protection to both parties.

22.2 Policy

BH requires all individuals who do not have a contract of employment to obtain appropriate access authority (e.g. HRC or LoA) before any direct contact with patients for the purposes of research.

BH appreciates that the process established by this policy places an administrative burden on those who need to work across a number of NHS organisations. It has, therefore, implemented the Research Passport scheme recommended by the Department of Health. This has established an agreed and secure procedure by which individuals need only be granted one honorary contract by an NHS organisation in order to carry out duties in any other NHS organisations where the original and standard honorary contract will be accepted.

Honorary contracts are not intended to grant any form of employment status with BH.

The responsibility for ensuring that honorary contracts or LoAs are in place rests with the BH consultant or other member of staff sponsoring the individual. They shall work in consultation with the JRMO, Clinical Director, Head of Nursing or General Manager of the appropriate clinical directorate or Medical Director or Director of Nursing and Quality.

BH's HR Department has an application form for the issue of Honorary Clinical Contracts and the JRMO will generally use the Research Passport Form as the appropriate document to initiate an application for an HRC or LoA. Each application must be sponsored by a consultant if the applicant is a medical or dental practitioner or by another senior member of staff for other applicants.

Applicants seeking access to the Trust for research purposes will be required to have undergone an evidenced occupational health assessment before an HRC or LoA is issued.

Applicants will also be required to supply an Enhanced Criminal Records Bureau check to the JRMO before an HRC or LoA is issued, in line with BH's arrangements for the protection of children and vulnerable adults.

It shall be the responsibility of the relevant substantive employer to arrange the required checks on behalf of its employees. Where applications are made to BH's HR Department in relation to an Honorary Clinical Contracts, BH will normally undertake these checks.

22.3 Application

This policy applies to all individuals who are not employees of BH who wish to have contact with patients or patient data for the purposes of conducting research. All principal investigators and support staff working on a research project who have direct contact with patients must be covered by an appropriate level of access (i.e. honorary contract or LoA).

The principal investigator is the designated lead who has overall responsibility for a research project. He or she will normally be the grant holder. Other staff associated with the research programme e.g. laboratory staff of other organisations should be considered on a case-by-case basis. However, in all instances staff with access to tissue and/or patient data will be bound by current regulations on confidentiality and data protection.

In accordance with the policy in this area recommended by the Department of Health, BH in agreement with other NHS Trusts will accept suitably qualified NHS staff who have undergone standard pre-employment checks to work on research projects authorised by the

JRMO. Each such person will be issued with a LoA in accordance with the NIHR Research Passport Scheme.

22.4 Concerns about non-BH researchers

Members of staff with concerns about researchers or other honorary contract holders working in their clinical area should raise these concerns with their line managers. If a delay in issuing approvals could result in potential harm to patients, staff or a breach of the law, individuals should raise the concerns with an appropriate professional lead or by using BH's whistle-blowing procedures.

Managers with issues of concern should check the name and details of the honorary contract holder or access holder and raise the concerns with the local sponsor or professional lead as soon as possible. The sponsor or professional lead will take action as appropriate, which may include ending the honorary appointment or access arrangement.

Individuals wishing to check whether proper reporting arrangements are in place for an honorary contract holder or access holder can check details with the JRMO.

Note: This policy applies only to BH

23. Misconduct [Pending update March 2016]

23.1 QMUL policy

23.1.1 Introduction and Scope

QMUL is a research-led Institution, recently ranked 11th in the UK in the Research Assessment Exercise, committed to maintaining the highest standards of integrity and probity in the conduct of research.

This Procedure is based on the Procedure for the Investigation of Misconduct in Research by the UK Research Integrity Office (UKRIO) and outlines the action to be taken when an allegation of misconduct in academic research is brought against any present or past member of staff of the University in respect of research undertaken while employed by the College. A separate procedure is in place for allegations of research misconduct against students.

The Procedure will provide a report that might require action using the College's disciplinary process or through other non-disciplinary processes. It is not intended to be used as part of any disciplinary or regulatory process, and should be viewed as a separate procedure.

23.1.2 Summary of Procedure

The Named Person is responsible for receiving allegations of misconduct in research, and for appointing a Named Investigator who carries out the detailed investigation of the complaint as outlined below. The Named Person is a nominee of the Principal (the role of the Named Person as outlined in the Procedure will be filled by the Senior Vice-Principal). The Named Investigator is appointed from the academic sectoral representatives on the College Research Board.

There shall be four stages of enquiries into an allegation:

1. **Registering the Complaint**: the Named Person receives and acknowledges the allegation;
2. **Preliminary Investigation**: the Named Person passes the allegation to a Named Investigator, who conducts a preliminary investigation to determine that the allegations fall within the definition of misconduct and the contractual status of the Respondent;
3. **Screening Stage**: by the Named Investigator, to gather information and evidence, and to determine whether there is *prima facie* evidence of misconduct in research; and
4. **Formal Investigation**: a panel is convened to examine all relevant facts to determine whether, on the balance of probabilities, misconduct appears to have occurred.

23.1.3 Stage One: Registering the Complaint

Allegations must be made in writing (where possible) to the Named Person accompanied by any supporting evidence.

Upon receipt of allegations of misconduct in research, the Named Person shall formally acknowledge receipt of the allegations by letter to the Complainant (and his/her representative by agreement), in which he/she shall also advise him/her of the Procedure that will be followed.

The Named Person shall pass responsibility for the investigation of a particular allegation to the appropriate Named Investigator.

23.1.4 Stage Two: Preliminary Investigation

(i) The Named Investigator shall review the nature of the allegations and, where they concern situations that require immediate action to prevent further risk or harm to staff, participants or other persons, suffering to animals or negative environmental consequences (where this might contravene the law or fall below good practice), then the Named Person shall take immediate appropriate action to ensure that any such potential or actual danger/illegal activity/risk is prevented/eliminated.

(ii) It may also be necessary to notify legal or regulatory authorities. As a consequence, the College may be required to comply with an investigation led by a legal or regulatory body, which will ordinarily take precedence over this Procedure.

(iii) Where allegations include behaviour subject to defined sanctions in the College's disciplinary process, then the Named Investigator shall take steps to implement that disciplinary process.

(iv) In both cases, this Procedure may continue in parallel but may have to be suspended, to be concluded later, or may have to be declared void by the Named Person.

(v) The Named Person or Named Investigator may consider that the situation presenting as misconduct may in fact be a result of a dispute or misunderstanding between individuals. Those situations not considered to be serious in nature might be resolved by informal discussion and/or arbitration and/or dispute resolution, without the requirement for a formal investigation. Where appropriate, opportunities to resolve matters through mediation should be considered. It may still be appropriate to conduct an initial investigation to establish whether the allegation may have sufficient substance to warrant a Formal Investigation of misconduct in research.

(vi) Where the allegations are within the definition of misconduct in research, the Named Investigator shall inform the Named Person, Principal, Head of Human Resources, Head of Research Grants Administration/Joint Research and Development Office and Academic Secretary or their nominees. They will be provided in confidence with the following information:

- The identity of the Respondent
- The identity of the Complainant
- Details of all sources of internal and external funding
- Details of all internal and external collaborators for the research in question
- Other details that the Named Investigator considers appropriate

(vii) The Named Investigator shall then, in conjunction with the Head of Human Resources and Head of Research Grants Administration/Joint Research and Development Office or their nominees, investigate the contractual status of the Respondent and the contractual details specific to the research project(s) related to the allegations.

(viii) The Named Investigator may need to contact the Respondent's primary employer, where an honorary contract is held and any external Sponsors, funding organisations and/or collaborators. The Named Investigator shall liaise with the Human Resources Department to ensure that the rights of the Respondent and Complainant, and the integrity of the investigation are not compromised by any such actions.

(ix) The Respondent shall be informed of the preliminary investigation in a confidential meeting, with a representative of the Human Resources Department in attendance and may be accompanied to this meeting by a colleague or trade union Representative. If the allegations are made against more than one Respondent, the Named Investigator shall inform each individual separately and not divulge the identity of any other Respondent. A summary of

the allegations in writing shall be given to the Respondent (and his/her representative by agreement) at the meeting, together with a copy of the Procedure to be used and the timeframe of the investigation.

(x) This Procedure aligns with the College's Whistleblowing policy. In accordance with that policy, the allegation and identity of the Complainant will be kept confidential so far as is reasonably possible by the Named Person/Named Investigator until any Formal Investigation is launched, save for the provisions in paragraphs 22.4.6 – 22.4.9 above.

23.1.5 Stage Three: Screening

(i) The Named Investigator shall ensure that all relevant information and evidence are secured, so that any investigation conducted under this Procedure can have access to them. This may include, but is not limited to:

a. Securing all relevant records, materials and locations associated with the work, copies of which shall be provided to the Respondent

b. Liaising with Human Resources and the relevant line manager(s) to:
- Request the temporary suspension of the Respondent from duties on full pay
- Request the temporary barring of the Respondent from part, or all, of the premises of the College and any of the sites of any partner organisation(s); and/or
- Request a temporary restriction be placed on the Respondent requiring him/her not to have contact with some or all of the staff of the College and those of any partner organisation(s)

(ii) Such actions shall only be taken where there is a clear risk to individuals or that evidence might be destroyed, and will take into account the Respondent's responsibilities for supervision, teaching and management. A review of any such action will be taken throughout the Procedure to ensure that it is not unnecessarily protracted. The implementation of this stage of the Procedure does not imply guilt.

(iii) Once initiated the Procedure will progress to the natural end-point irrespective of:

a. The Complainant withdrawing the allegations at any stage

b. The Respondent admitting, or having admitted, the alleged misconduct, in full or in part

c. The Respondent or the Complainant resigning, or having already resigned, his/her post

(iv) All contributions to the process of screening will be recorded and maintained for subsequent use. As part of the Screening Stage the Named Investigator will:

a. Review the submission and supporting evidence provided by the Complainant

b. Review the evidence and supporting documentation from the Respondent

c. Review any background information relevant to the allegations

d. Interview the Respondent, the Complainant and other individuals who might provide relevant information

e. Produce a report of the findings of the Screening Stage

(v) The Screening Stage will normally aim to be completed within 30 working days from the receipt of the allegations.

(vi) When there is clear evidence of an infringement that might contravene the College's disciplinary code, the Named Investigator will consult the Head of Human Resources on the full and accurate transfer of all case information to

the disciplinary process. A full written record shall be kept of this decision. When the Named Investigator considers that the allegations are sufficiently serious and have sufficient substance to warrant recommending a Formal Investigation, the Named Investigator shall take immediate steps to set up a Formal Investigation.

(vii) When the allegations have some substance, but due to a lack of clear intent to deceive or due to their relatively minor nature, the matter shall be addressed through the College's competency, education and training mechanisms, or other non-disciplinary processes, rather than through the Procedure's Formal Investigation stage. The investigation using the Procedure would then conclude at this point.

(viii) If the Named Person decides that the allegations are mistaken, frivolous, vexatious and/or malicious, the allegations will then be dismissed. This decision shall be reported in writing to the Respondent and all the parties who had been informed initially.

23.1.6 Stage Four: Formal Investigation

(i) The Investigation Panel shall examine the evidence collected during the Screening Stage following the original allegations and investigate further as required.

(ii) The Named Investigator shall inform the following (or their nominees) that a Formal Investigation of the allegations is to take place:

a. Respondent (and his/her representative by agreement)
b. Complainant (and his/her representative by agreement)
c. Named Person
d. Principal
e. Head of Human Resources
f. Head of Research Grants Administration
g. Academic Secretary
h. Named Person of any Partner Organisation with which either the Respondent and/or Complainant has an honorary contract, and through him/her the Heads of Organisation, Personnel and Research

(ix) The Investigation Panel must be appointed within 30 working days of the Named Investigator recommending a Formal Investigation. The Investigation Panel will not work to a prescribed timetable but will work as quickly as possible without compromising the Principles of the Procedure.

(x) The Investigation Panel shall consist of at least three, and always an uneven number of, senior members of staff. In selecting the panel the Named Investigator shall take into consideration the subject matter of the allegations and any potential conflicts of interest.

(xi) It is a requirement that one or more members of the Investigation Panel be selected from outside the College, particularly where allegations are especially serious or involve senior staff. Such external members replace internal members of the Investigation Panel rather than being in addition to them.

(xii) At least two members of the Panel shall have experience in the area of research in which the alleged misconduct has taken place, although they shall not be members of the Department concerned. Where allegations concern highly specialised areas of research the Investigation Panel shall have at least one member with specialised knowledge of the field. It is desirable, but not essential, for the Panel to include a member who either holds or has held judicial office or to be a barrister or solicitor of at least ten year's standing.

(xiii) The Principal, or his nominee, shall approve the panel members and may veto nominations for the Investigation Panel, recording the reason for the veto in writing and communicating it to all parties.

(xiv) Once convened, the membership of the Investigation Panel shall not be changed or added to. Members who are not able to continue will not be replaced. In the event that the Chair stands down or the membership falls below three, the Named Investigator will take steps to recruit additional members or re-start the Formal Investigation process.

(xv) To perform its task the Investigation Panel shall:

a. Review the submission(s) and supporting evidence provided by the Complainant
b. Review the response(s) and supporting evidence from the Respondent
c. Review background information relevant to the allegations
d. Review any interviews conducted with the Respondent, the
e. Complainant, and other staff who may provide relevant information to assist the Investigation Panel
f. Call expert witnesses to give advice if necessary
g. Seek guidance from UKRIO and its advisers, where necessary

(xvi) The Investigation Panel shall be serviced by the Academic Secretariat, through whom all documentation and all other communication should be passed.

(xvii) Communication, either written or oral, by any party (to include Respondent, Complainant or any other member(s) of staff) directly with members of the Panel will not be admitted as part of the documentation relating to the case except when it takes place at the request of the Panel, or at formal meetings called by the Chair of the Investigation Panel.

(xviii) A Formal Hearing will be held during which the Respondent will be given the opportunity to set out his/her case and respond to the allegations made against him/her. He/she will be allowed to ask questions, to present evidence, call witnesses and raise points about any information given by any witness (including the Complainant). The Complainant and other staff may also be invited to provide evidence when members of the Panel consider that it may have relevance to the investigation.

(xix) The Chair shall report the progress of the Investigation Panel to the Named Investigator by the Chair on a bi-weekly basis. If it is believed that the investigation will take more than one calendar month, progress reports shall be made on a monthly basis.

(xx) The Investigation Panel shall provide a draft report of its findings to the Named Person, who will make it available to the Respondent and the Complainant for comment on the factual accuracy of the report. Modifications will only be made when the report contains errors of fact and matters that have bearing on the facts.

(xxi) The Investigation Panel shall then provide to the Named Investigator a final report that:

a. Summarises the conduct of the investigation
b. States whether the allegations of misconduct in research have been upheld in whole or in part, giving the reasons for its decision and recording any differing views
c. Makes recommendations in relation to any matters relating to any other misconduct identified during the investigation
d. Addresses any procedural matters that the investigation has brought to light within the College and relevant partner organisations and/or funding bodies

(xxii) In addition to reaching a conclusion over the nature of the allegations, the Investigation Panel may make recommendations with respect to:

a. Whether the allegations should be referred to the relevant organisation's disciplinary process

b. Whether any action will be required to correct the record of research
c. Whether organisational matters should be addressed by the College through a review of the management of research
d. Other matters that should be investigated

(xxiii) The Named Investigator shall inform the following of the conclusion of the Formal Investigation:
a. The Respondent and the Complainant
b. The Named Person, Principal, the Head of Human Resources, the Academic Secretary, the Head(s) of the relevant Department(s) and any other relevant members of staff
c. If the Respondent and/or the Complainant are employed on joint clinical/honorary contracts, the Named Person, the Head of Personnel and the Head of Research of the other organisation(s)
d. Where appropriate, the responsible person within any relevant partner organisations, funding bodies and/or regulatory or professional bodies

(xxiv) Evidence of further, distinct instances of misconduct in research by the Respondent, unconnected to the allegations under investigation; or misconduct in research by another person or persons, shall be submitted to the Named Person in writing, along with all supporting evidence, for consideration under the initial steps of the Procedure.

23.1.7 Outcomes

If all or any part of the allegations are upheld, the Named Person, the Head of Human Resources and at least one other member of senior staff shall then decide whether the matter should be referred to the College's disciplinary process or for other formal actions.

If the allegations are deemed to be frivolous, vexatious and/or malicious the Named Person shall consider recommending to the appropriate authorities that action be taken under the College's disciplinary process against anyone who is found to have made frivolous, vexatious and/or malicious allegations of misconduct in research.

The Respondent shall not have the option of appealing against the report of the Investigation Panel. The Respondent has the statutory right of appeal if the matter is referred to the College's disciplinary process.

23.1.8 Following the Investigation of Research Misconduct

23.1.8.1 Disciplinary Process

If the allegations proceed to the College's disciplinary process, the report of the Investigation Panel shall form the basis of the evidence that the Disciplinary Panel receives. All the information collected and brought to light through the Procedure will be transferred to the disciplinary process.

23.1.8.2 Records

The Named Investigator shall be responsible for keeping a written record of all decisions taken throughout all the steps of the Procedure, in conjunction with the Academic Secretariat. The Chair of the Investigation Panel shall assume responsibility with the Academic Secretariat for keeping accurate records of the activities, deliberation and reporting of the Panel. The Academic Secretariat will maintain the file for the case and archive this appropriately at the completion of the Procedure.

23.1.8.3 Specialised research

It is recognised that the subject area of certain cases may be so specialised as to require equally specialised advice as to how to resolve or correct matters arising from

the misconduct in research; the recommendations and experience of the Investigation Panel may prove particularly useful if this is the case.

23.1.8.4 Support provided to the Complainant

Where allegations have been upheld (in full or in part), or found to be mistaken but not frivolous, vexatious and/or malicious, then appropriate support, guidance and acknowledgment shall be given to the Complainant, given that his/her role in the process will most likely have been stressful and may well have caused friction with colleagues. The Named Person shall take whatever steps he/she considers necessary to support the reputation of the Complainant. For example, if the case has received any publicity, the Complainant shall be offered the possibility of having an official statement released for internal and/or external purposes.

23.1.8.5 Support provided to the Respondent

Where allegations have not been upheld (in full or in part), the Named Person shall take such steps as are appropriate, given the seriousness of the allegations, to support the reputation of the Respondent and any relevant research project(s). Appropriate support and guidance shall be given to the Respondent, given that his/her role in the process will most likely have been stressful and may well have caused friction with colleagues. As above, where the case has received any publicity, the Respondent shall be offered the possibility of having an official statement released for internal and/or external purposes.

23.1.8.6 Handling wrongful allegations

If the Investigation Panel has found that the Complainant's allegations were frivolous, vexatious and/or malicious, the Named Person will consider recommending that action be taken against the Complainant, under the College's disciplinary process.

23.1.8.7 Other actions that may be required or be considered appropriate

Following the conclusion of the Procedure, the Investigation Panel may need to recommend additional measures in addition to those that may be taken by way of the College's disciplinary process. Any such recommendations will be actioned through the College's management structure. This may include:

a. Retraction/correction of articles in journals
b. Withdrawal/repayment of funding
c. Notifying patients/patients' doctors of any potential medical issues that may arise
d. Notification of misconduct to regulatory bodies (such as the MHRA, the Healthcare
e. Commission, the Home Office [for research involving animals], professional bodies, etc.)
f. Notifying other employing organisations
g. Notifying other organisations involved in the research, such as funding bodies
h. Adding a note of the outcome of the investigation to a researcher's file for any future requests for references; and/or
i. Review internal management and/or training and/or supervisory procedures for research

23.2 BH policy

The validity of research and other academic endeavour is based on the implicit assumption of honesty and objectivity by the research investigator and on the explicit premise that research data can be verified. Both the Trust and Universities working in partnership must uphold this principle and endeavour to maintain public trust in the research process. As stated by the DoH[42], *'Employers of staff undertaking health and social care research have responsibility for developing and promoting a quality research culture in their organisation and for ensuring that their staff are supported in, and held to account for, the professional conduct of research… dealing with non-compliance or misconduct, and learning from complaints.'*

This policy recognises the need for the BH and QMUL to augment its standard policies and guidelines to address issues relating to misconduct in research. The guidelines should be read in conjunction with the Trust Disciplinary Policy, Whistle-blowing Policy and where appropriate the Standards of Business Conduct, Grievance policy, Harassment Policy and Investigations Policy. These policies apply to researchers who are employees of the Trust or other University or NHS employees holding honorary contracts and engaged in clinical research activities within the Trust. The College's Procedure for Investigating Allegations of Misconduct in Academic Research should also be considered with these policies.

'Research misconduct' includes research fraud, non-disclosure of research fraud, violations of Trust research policies including this policy, violations of ethical approval, financial probity, and local procedures for approval of research and indemnity arrangements.

'Research fraud' includes: the intentional fabrication or falsification of research data; the omission in publications of conflicting and/or non-conforming observations or data; the theft of research methods or data from others; the plagiarising of research ideas, results or publication(s); or other failure to follow established protocols, deviations from accepted practices in carrying out or reporting results from research.

In the case of misconduct, some professional groups will be subject to disciplinary action by their professional bodies as follows:

- Doctors are responsible to the General Medical Council;
- Nurses, health visitors and midwives are responsible to the United Kingdom Central Council;
- State registered practitioners are responsible to the individual board of the Council for Professions Supplementary to Medicine; and
- Social care professionals will be one of the responsibilities of the General Social Care Council.

23.2.1 Policy

All NHS employees of other Trusts who carry out research using Trust patients, patient samples, patient records, premises, facilities, staff and services must be bound by Trust policies and hold a current Trust honorary contract or Letter of Access for Research with clear lines of accountability, see section 21 (Access to Work at NHS sites: Honorary Research Contracts and Letters of Access). The Trust and College will inform their opposite HR Departments (or those of other organisations) immediately upon notification that an

[42] Research Governance Framework for Health and Social Care. DoH, March 2004.

allegation of misconduct has been reported. Suitable arrangements between the organisations will then be made to address the allegations.

Researchers must fulfil their responsibilities as outlined in the Research Governance Framework for Health and Social Care1. Main responsibilities include;

- Ensuring that any research undertaken follows the agreed protocol;
- Helping care professionals to ensure that participants receive appropriate care while involved in research; and
- Protecting the integrity and confidentiality of clinical and other records and data generated by the research and for reporting any failures in these respects, adverse drug reactions and other events or suspected misconduct through appropriate systems the principal investigator must accept a key role in detecting and preventing scientific misconduct by adopting the role of guarantor on published outputs.

Researchers must comply with and aid in any necessary monitoring and auditing of research projects required by the JRMO. Any complaints, incidents or risks relating to research must be reported through the normal BH/ QMUL mechanisms and brought to the attention of the Director for Research Development, the relevant Officer within the University or other organisation and the JRMO. Any such complaints, incidents or risks should be logged by the JRMO. All investigations will be carried out with due regard to the following:

- The overall responsibility for the investigation will lie with a suitably qualified and experienced member of staff;
- An appropriate investigation will be conducted that is commensurate with the scale of the allegations;
- In the case of research fraud the appropriate clinical lead must be informed of all the allegations made and of the final outcome of the investigation;
- Where appropriate any external funding organisations and / or collaborating organisation must be notified and kept informed. Individuals who are suitably qualified and able to comment on any relevant clinical information, research data and publications will judge the evidence collected during the course of the investigation;
- Where appropriate, the investigation will include previous work by the researcher and the researcher will be requested to withdraw all pending related abstracts and manuscripts if found fraudulent, and whilst the research is under investigation;
- The Medical Director will take the necessary action recommended by the findings from the investigation including referral to the relevant professional body, where appropriate; and
- Individuals suitably qualified and experienced to comment on any relevant clinical information, research data and publications will hear any appeal.

23.3 Definitions

Accepted Procedures (for research) include but are not limited to the following:

a. Gaining informed consent where required
b. Gaining formal approval from relevant organisations where required
c. Any protocols for research contained in any formal approval that has been given for the research
d. Any protocols for research as defined in contracts or agreements with funding bodies and sponsors
e. Any protocols approved by the Medicines and Healthcare products Regulatory Authority (MHRA) for a trial of medicinal products
f. Any protocols for research set out in the guidelines of the College and other relevant partner organisations
g. Any protocols for research set out in the guidelines of appropriate recognised professional, academic, scientific, governmental, national and international bodies

h. Any procedures that are aimed at avoiding unreasonable risk or harm to humans, animals or the environment
i. Good practice for the proper preservation and management of primary data, artefacts and materials
j. Any existing guidance on good practice on research

The **Complainant** is a person making allegations of misconduct of research against one or more Respondents.

An **honorary contract** can be issued to:
a. A clinical academic working in both a university and an NHS organisation, in which case the NHS organisation would issue the honorary contract
b. An NHS consultant with an arrangement to undertake teaching and/or research in a university, in which case the university would issue the honorary contract
c. A researcher employed by a university and undertaking a research project in an NHS organisation, in which case the NHS organisation would issue the honorary contract

Misconduct in research is taken to include:
a. Fabrication
b. Falsification
c. Misrepresentation of data and/or interests and or involvement
d. Plagiarism
e. Failures to follow accepted Procedures or to exercise due care in carrying out responsibilities for:
    - Avoiding unreasonable risk or harm to:
        i. humans
        ii. Animals used in research; and
        iii. The environment
    - The proper handling of privileged or private information on individuals collected during the research.

The **Named Person** is the individual nominated by the College to have responsibility for receiving any allegations of misconduct in research; initiating and supervising the Procedure for investigating allegations of misconduct in research; maintaining the record of information during the investigation and subsequently reporting on the investigation to internal contacts and external organisations; and taking decisions at key stages of the Procedure. The Named Person shall be a senior member of staff with significant knowledge and experience of research but should not be the Principal; the Head of Research; or the Head of Human Resources.

The **Respondent** is the person against whom allegations of misconduct in research have been made.

The **standard of proof** used by the Investigation Panel is that of “on the balance of probabilities.”

23.4 Principles

a) Those responsible for carrying out this Procedure must be aware that there may be occasions when a balance has to be struck in the application of the Principles: for example, it may, in certain circumstances prove to be impracticable to undertake a detailed screening of the allegations without releasing the Complainant’s identity to the Respondent.

b) The Named Person should be responsible for resolving any such conflicts between the Principles, keeping in mind at all times that the primary goal of this Procedure is

to determine the truth of the allegations. The Named Person can seek guidance from UKRIO and other bodies, as well as seeking legal advice.

c) The confidential nature of the proceedings is essential in order to protect the Complainant, the Respondent and others involved in the Procedure. It is important that in the conduct of an investigation using this Procedure that the principles of confidentiality and fairness are applied with appropriate balance for both the Respondent and the Complainant.

d) The identity of the Complainant or the Respondent should not be made known to any third party unless:
   (i) It has been deemed necessary (by those conducting the investigation) in order to carry out the investigation;
   (ii) It is necessary as part of action taken against the Respondent when (at the end of the Procedure and the College's disciplinary/appeals processes) the allegations have been upheld;
   (iii) It is necessary as part of action taken against a person who has been found to have made malicious, vexatious or frivolous allegations;
   (iv) It is the stated policy of the employer/funder/other national body that the identity of individuals proved through appropriate disciplinary and appeals processes to have committed misconduct in research should be made public.

e) Any disclosure to a third party of the identity of the Complainant or Respondent, or of any other details of the investigation, should be made on a confidential basis. The third party should understand this, and that he/she must respect the confidentiality of any information received. Breaching confidentiality may lead to disciplinary action, unless covered by the Public Interest Disclosure Act and/or the College's own grievance or whistle-blowing procedures.

f) The investigation of any allegations of misconduct in research must be carried out fairly and in accordance with the statutory human rights of all parties involved. Those responsible for carrying out this Procedure should do so with knowledge of:
   (i) The statutory obligations of the College and the rights of employees according to current law
   (ii) Any additional rights and obligations particular to the institution and/or its employees – for example those bestowed by university statutes and ordinances.

g) Those responsible for carrying out the Procedure should recognise that failure to transfer information could lead to the process being unfair to the Respondent and/or the Complainant.

h) In using this Procedure, and in any action taken as a result of using the Procedure, care must be taken to protect:
   (i) Individuals against frivolous, vexatious and/or malicious allegations of misconduct in research
   (ii) The position and reputation of those suspected of, or alleged to have engaged in, misconduct, when the allegations or suspicions are not confirmed
   (iii) The position and reputation of those who make allegations of misconduct in research in good faith, i.e. in the reasonable belief and/or on the basis of supporting evidence that misconduct in research may have occurred

Note: This policy applies to BH and QMUL as indicated.